Exhibit B

UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

MDL NO. 2875

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

ALL ACTIONS

DEPOSITION OF ZIRUI SONG, MD, Ph.D.

TUESDAY, FEBRUARY 8, 2022

Deposition of ZIRUI SONG, MD, Ph.D. in the above-mentioned matter before Jomanna DeRosa, a Certified Court Reporter (License No. 30XI00188500), and Notary Public of the State of New Jersey, taken via Zoom at Harvard Medical School, 180 Longwood Avenue, Boston, Massachusetts 02115 on Tuesday, February 8, 2022 commencing at 9:14 a.m.

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ALSO PRESENT: JUSTIN BILY, VIDEOGRAPHER

I N D E X

E X H I B I T S

(All exhibits are attached hereto.)

THE VIDEOGRAPHER: We are going on the record at 9:14 on February 8th, 2022. This is media unit No. 1 of the video recorded deposition of Dr. Zirui Song regarding the Valsartan litigation. My name is Justin Bily from the firm Veritext and I'm the videographer. The court reporter is Jomanna DeRosa from the firm Veritext. All counsel will be noted on the stenographic record. Would the court reporter please swear in the witness and then we can begin.

ZIRUI SONG, MD, Ph.D., having offices at Harvard Medical School, 180 Longwood Avenue, Boston, Massachusetts 02115, having first been duly sworn by the Notary, then testified as follows:

DIRECT EXAMINATION
BY MR. TRISCHLER:

Q. Good morning, Dr. Song. Can you hear me?
A. Yes, sir, good morning.
Q. You already provided this information to the court reporter off the record, but I'd like to get it on our transcript, if we can. Could you start by just giving me your full name?

A. Yes. My first name is Zirui, Z-I-R-U-I, and my last name is Song, S-O-N-G.
Q. And your professional address, please. I only need one of them.
A. My address at Harvard Medical School is 180 Longwood Avenue, Boston, Massachusetts 02115.
Q. I know that you've been deposed on a few prior occasions. Is that correct?
A. Yes.
Q. How many depositions have you given before today?
A. Two.
Q. One of those depositions was in a case called Anderson versus Lab Corp. Is that correct?
A. Yes.
Q. What was the other deposition?
A. I don't remember the full name, but the defendant was Quest Laboratories.
Q. In the Anderson versus Lab Corp. matter, were you retained as an expert witness for one of the parties to that litigation?
A. Yes, I served as an expert witness for the plaintiffs.
Q. And what was the nature and scope of your opinion testimony that you sought to offer in

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the Anderson matter?
A. Well, I believe you have my report, or rather my transcript in full for that matter, so you could probably answer that question by looking at it. If I were to quickly summarize for you, it was regarding surprise billing.
Q. Were you -- did you offer the opinion that the billing practices of Lab Corp. were inappropriate in some manner or form?
A. To be precise, my expert opinion in that case pertained to the reasonableness of pricing; specifically, in regards to surprise billing.
Q. And in the Quest matter, were you also serving as an expert witness in that piece of litigation?
A. Yes, similarly for the plaintiffs as well.
Q. And what was the nature of your opinion testimony in the Quest matter?
A. Substantively analogous to my response to you regarding in the first matter.
Q. So in both prior depositions that you gave, your testimony focused on the reasonableness of lab charges provided by two labs; one being Quest and one being Lab Corp.. Correct?

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A. As a general summary, I would agree with that.
Q. Have you ever been designated as an expert witness to offer opinion testimony in any other civil proceeding, aside from the Valsartan litigation that brings us here today and the two cases that you just told me about?
A. I have not offered a deposition in any other court case; although, I have been retained as an expert witness in other cases.
Q. In other cases where you've been retained, have you written a report similar to what you have done in this case where your opinions were disclosed and produced to the other side in that litigation?
A. Yes.
Q. On how many occasions have you written an expert report as a disclosed expert for litigation purposes?
A. In addition to the two cases that we just discussed?
Q. Yes, sir.
A. There are two additional cases for which I have produced an expert report.
Q. Can you tell me about those two cases, please?

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A. As part of your request, I submitted to counsel the full names of those cases, so I believe you have that in your possession. Substantively, those cases also pertain to surprise billing.
Q. I may have the cases in my possession, but I can assure you I don't know the names as I sit here and ask you the questions. So, do you know the names of those other two cases?
A. Again, I don't recall the full name off the top of my head, but the defendants in one of the two cases is an emergency medicine set of providers and that case pertained to surprise billing in emergency department care. And the other of the two cases pertained to surprise billing in anesthesia care for which the defendants were a group of anesthesia care providers.
Q. And did the same law firm retain you in all four of these cases?
A. Yes.
Q. What was that law firm?
A. Wolf Popper (Sic Wolf Popper LLP).
Q. Was there a particular attorney or attorneys at Wolf Popper that you worked with on those cases?

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A. There was a group of attorneys with whom I interacted during those cases.
Q. Can you tell me the names of the attorneys in that group, please?
A. Well, off the top of my head, the attorney with whom I interacted the most was probably David Nicholas. Another of his colleagues with whom I interacted quite often was Matthew Insley-Pruitt, another colleague was Timothy Brennan, another colleague was Chet Waldman. The only other colleague I can remember off the top of my head is Patricia Avery and I may be forgetting a person or two.
Q. What's the status of those four surprise billing cases, as you called them?
MR. MIGLIACCIO: I'm going to object to the extent that it's vague and may call for a legal conclusion. And I think you can answer to your knowledge, Dr. Song.

(Whereupon, the requested portion of the record was read by the reporter.)

THE WITNESS: I am not an attorney in those cases, so I do not know that my most up to date knowledge from my own perspective as an expert

witness is the current status of any of those cases. But, to my knowledge, I believe, as far as I understand from the last time I received updates from counsel --

MR. MIGLIACCIO: I do want to caution you, Dr. Song, to not disclose any communications that might not be public with respect to those cases. Those communications might be privileged under Rule 26 with the lawyers that you're working with in those cases, so I want to caution you in that regard.

THE WITNESS: Understood, thank you. And I was going to finish that statement by just saying that they are ongoing at this time.

BY MR. TRISCHLER:

Q. As the -- has your opinion been challenged in any of those proceedings, if you know?

A. What do you mean by "challenged"?

Q. Are you aware of whether or not the defendants in any of those proceedings have challenged the admissibility of your testimony, methodology that you used, or the reliability of your testimony? If you don't know, you don't know. But if you know, I'd like to know what the answer is.

A. Well, I'm not a lawyer, so I just wanted

to understand the definition of "challenged" because I have certainly received and read expert reports from the defense in some of those cases, not all of them. And if that's what you mean by "challenged", there are expert reports from the defense in those cases, but I have not, to my knowledge, been challenged in a different definition of challenged.

Q. Have you been made aware of any motion filed by the defendants seeking to strike or preclude your testimony for any reason?

A. No, I have not.

Q. Are any of the lawyers at Wolf Popper involved in the Valsartan litigation, to your knowledge?

A. To my knowledge, no.

Q. How did you become involved in the Valsartan litigation?

A. I was approached by Greylock McKinnon Associates with a question about my interest in serving as an expert witness in this litigation.

Q. Who approached you at Greylock McKinnon?

A. Renee Rushnawitz.

Q. Tell me who Ms. Rushnawitz is?

A. If I recall correctly, she is the managing director of GMA.

Q. And by GMA, for our record, you're referring to Greylock McKinnon and Associates (Sic Greylock McKinnon Associates)?

A. Yes.

Q. What information did Ms. Rushnawitz provide you regarding the Valsartan litigation and what role they were looking to fill?

A. Given that the initial request or question came in probably in September of 2021, I don't recall her exact wording at that time, but it was about my interest in serving as an expert witness on the issue of the pricing of medical services.

Q. And since you're here today and I'm talking to you through a computer, my guess is you indicated to her that you would have some interest in looking at the matter?

A. I would agree with your characterization.

Q. Did Ms. Rushnawitz then put you in contact with some lawyers?

A. I believe the next step was that I had a conversation with counsel, whom you see here today, Nick and Mark in particular.

Q. And can you be more specific with last names, please, because there's a great deal of

lawyers involved for all the parties in this case, so I want to make sure we have it for the record. What lawyers did you have a conversation with?

A. Recalling back to September of last year, I believe the next step after Renee's initial question was a discussion with Mr. Migliaccio and Mr. Patronella.

Q. I marked as Exhibit No. 1 a copy of the Notice of Deposition that brings us here today. Our tech can put it up on the screen and it's available to you in the chat.

(Whereupon, Exhibit ZS-1 was marked for identification.)

BY MR. TISCHLER:

Q. Have you seen the Notice of Deposition before, sir?

A. Yes, I have. I'm not able to scroll to the next pages, so I'm only seeing the first page of a document.

Q. Well, I think if you go into the chat, you should able to see the whole document as we discussed. My only question I have right now is have you seen this notice before?

A. I just loaded it from the link that you provided and, yes, I have seen it before.
Q. Since you've seen it before, you know that I asked you to provide certain materials in connection with this deposition, including documents relating to your retention in this litigation. Correct?
A. The list of requested materials, yes, I have read through that previously and believe that I have provided, through counsel, everything that you have asked for here.
Q. Right. And I just want to make sure one of the things that I asked for was documents relating to your retention. Do you agree?
A. Which paragraph is that?
Q. I honestly don't have it in front of me, but we can go through it if need be.
MR. TISCHLER: Scroll down, please. Further.

BY MR. TISCHLER:
Q. No. 14 was: "All consulting contracts and/or retention letters concerning your involvement in this Case between you and any other person or entity, including but not limited to Plaintiffs'

lawyers or any other organization." Right?
A. Thank you for zooming in on that, yes.
Q. All right. And I'll mark as Exhibit No. 2 a copy of a retention agreement that was provided to me on the letterhead of Greylock McKinnon Associates. Do you see that?

(Whereupon, Exhibit ZS-2 was marked for identification.)

THE WITNESS: Yes, I see it here.
Q. And it's dated October 18, 2021, a little less than four months ago. Correct?
A. Yes, that's what it says here.
Q. And you told -- and you explained to us that you were initially approached by Renee Rushnawitz at Greylock McKinnon. Tell us, who is Greylock McKinnon?
A. To my understanding, they are a litigation consulting firm that supports the work of expert witnesses.
Q. Are you employed with Greylock McKinnon?
A. Not employed, no.
Q. You don't have any ownership stake in that company?

A. No.
Q. What is your affiliation with them, if any?
A. Only as an expert witness who works with some of the staff members of Greylock McKinnon Associates for the purposes of my expert witness activities.
Q. In this case, I'm trying to understand the nature of the relationship. In this case, as I understand it, you're billing for work you do at the rate of about $800 an hour. Is that correct?
A. That is printed on this agreement, yes.
Q. I know it's printed on the agreement. Is that the rate you're charging?
A. Yes, it is.
Q. So how much of that do you get and how much of that does Greylock McKinnon get?
A. My rate here is what is sent to me. To my knowledge, when Greylock McKinnon Associates works on litigation, they separately bill for the time and effort of their staff members.
Q. So whatever you bill, you keep. Whatever they bill, they keep?
A. Essentially, I would agree with that.
Q. And I think you mentioned that Greylock

McKinnon advertises their business as economists and consultants for lawyers. Right?
MR. MIGLIACCIO: Objection. Misstates testimony. You can answer.
THE WITNESS: Well, I honestly don't know how Greylock McKinnon Associates advertises themselves. I have not seen or been aware of an advertisement from them. I'm aware only of my working relationship with them, which is that of an expert witness who works with some of their staff members in the cases that I have been retained in.
Q. Do you know if Greylock McKinnon does anything other than provide support services to lawyers in litigation?
A. To my knowledge, that is their main professional activity. I'm not aware of other professional activities that the firm conducts.
Q. Have you ever been on their website?
A. Probably, a couple of years ago, perhaps.
Q. And you agree the website is a form of advertising. Right?
A. Depends on how one interprets a website. When I visited their website, I may have only been there for informational purposes to learn about them,

but I may not have perceived that information as advertisement.

Q. When you visited their website, did you note that Greylock McKinnon described their business as one that specializes in litigation support?

A. That sounds consistent with how I understand their work to be or the nature of their work, so I would not disagree with that. However, I don't recall off the top of my head the exact wording of their website material.

Q. When did you establish a business relationship with Greylock McKinnon?

A. I believe either 2019 or 2020.

Q. How many referrals have you received through them?

MR. MIGLIACCIO: Objection. Vague.

THE WITNESS: Would you mind defining "referrals", please?

BY MR. TRISCHLER:

Q. How much business have you received from them?

A. Would you mind defining "business", please? Do you mean the number of cases I have been invited or asked to consider participating in as an

expert?

Q. Sure, you can answer that question.

A. At the direct request of Greylock McKinnon Associates, two cases to date.

Q. One being Valsartan?

A. Yes, sir.

Q. In the other case that you looked at on referral from Greylock McKinnon, have you been disclosed or identified as an expert in that matter?

A. Yes, I have offered my services as an expert witness. The counsel in that other case has accepted. And I believe we have an agreement in place for expert witness work.

Q. Okay. I appreciate that and I'm trying to be mindful of privileges, so let me ask more precisely. While you've been retained by a lawyer in that other case that you were contacted through Greylock McKinnon, have you written a report or been disclosed to the other side as an expert?

A. I have not yet written a report.

Q. You -- according to the retention agreement that is marked as Exhibit No. 2, Greylock was retained in October of 2021. And based on this retainer agreement, I take it that your work in connection with this assignment would have begun

sometime on or after October 18, 2021. Is that fair to say?

A. That is fair to say, yes.

Q. And since beginning work on this matter in October of 2021, you billed at a rate of $800 per hour. Correct?

A. Correct.

Q. And what was your understanding of what it was that you were asked to do when you were retained back in October of 2021?

A. Again, as noted earlier, I was asked to provide an expert opinion regarding the pricing of medical services.

Q. I'm looking at the first paragraph of Exhibit 2 which, again, is the retention agreement and it reads: "I am writing to confirm our agreement that your firms, on behalf of Valsartan Plaintiffs' Executive Committee MDL 2865 (Sic MDL 2875) have retained Greylock McKinnon Associates to provide consulting on economic issues and other related services and, should it become appropriate, for Dr. Zirui Song to provide expert testimony in the matter referenced above on behalf of Plaintiffs as it relates to monitorizing a monitoring -- as it relates to monetizing", excuse me, "a monitoring protocol."

With that correction at the end, did I read that correctly?

A. Yes, I believe you read this paragraph correctly.

Q. All right. Is that a fair summary of what you understood your task to be when you were retained and became involved in this litigation in October of 2021?

A. The phrase here "monetizing" is what I mean by "pricing" in my earlier response to you. In my mind as a trained health economist, when I think about pricing, the more colloquial or layperson term for that may be "monetizing", so that matches my recollection of what I was asked to do. A monitoring protocol is what I think about, in my mind, as a potential set of medical services. So when I said "the pricing of medical services", you can take that to be synonymous for "monetizing a monitoring protocol".

Q. And after you were retained in this matter in October of 2021, Greylock McKinnon has apparently issued just one invoice reflecting your work in this case. Is that true?

A. To date, yes.

MR. TRISCHLER: Can we mark that invoice

as Exhibit 3, please.

(Whereupon, Exhibit ZS-3 was marked for identification.)

BY MR. TRISCHLER:

Q. And can we -- and can I assume that the information conveyed in this invoice is accurate, Dr. Song?

A. Give me a moment to review this exhibit, please. I would say yes, you can assume that the information here is accurate.

Q. All right. As a healthcare economist, I'm sure you can attest to the importance of fair, accurate and reasonable billing. Correct?

A. Well, that's a rather general statement, sir, but I would certainly support the principal that when one bills, that the information on the bill ought to be accurate.

Q. So I assume then, that the information on Exhibit No. 3 is a fair and honest summary of the time that you devoted to the task at hand?

A. Certainly, for the time that I've devoted and reported, but I was not the person who generated the number of hours submitted by the staff

of GMA, which is subsequent to this highlighted section.

Q. The highlighted section that we're looking at now on Exhibit 3 is the section that summarizes the time that you've devoted to the task. Correct?

A. Correct.

Q. And prior to preparing the report that was provided to myself and the other lawyers representing defendants to this litigation, you would have spent a grand total of 41 and a half hours working on this matter. True?

A. I didn't catch exactly your full question, but let me answer that to the best of what I heard. The number of hours here reflects exactly the dates printed on the sheet; essentially, October and November of 2021. So it's correct that all of my work since the retainer agreement was signed through the writing of the report is captured here in this total.

Q. So you were, just to put this in sort of a chronological order for my relatively unsophisticated mind to understand, you were retained on October 18, 2021, and asked to provide opinion testimony about monetizing a monitoring protocol.

Right?

MR. MIGLIACCIO: Objection. Misstates testimony.

THE WITNESS: Again, the synonymous phrase that I used for you earlier, and which I've recommended to you as a synonym to what you just read off, is the pricing of medical services. That's the work that I was retained to do.

BY MR. TRISCHLER:

Q. And you were retained to do that work on October 18th, 2021. Right?

A. Yes, per the earlier letter that we reviewed.

Q. And then three weeks later, approximately three weeks later, on November 10, 2021, you prepared a report that was filed with the court in the Valsartan litigation and provided to the defendants to this action and we've marked that report as Exhibit 4 to the deposition. Do I have that right?

(Whereupon, Exhibit ZS-4 was marked for identification.)

MR. MIGLIACCIO: You haven't shown that yet, right, Clem? Am I missing something?

MR. TRISCHLER: I haven't shown it yet, no.

MR. MIGLIACCIO: Okay. Fair enough. Yeah, being remotely, we don't see you marking.

MR. TRISCHLER: No, I understand. I'm old fashioned. I still use old lingo, so I guess I'll rephrase the question because I'm not trying to confuse you, Dr. Song.

BY MR. TRISCHLER:

Q. The report that you prepared in this matter is dated November 10, 2021. Correct?

A. That sounds correct from my recollection. If you would like me to confirm the exact date, then I would ask that we just look at the report together.

Q. Well, I've asked that it be marked as Exhibit No. 4. It should be in the chat now for you to look at. Obviously, you're more than welcome to confirm that date.

A. I'm pulling it up now. On Page 27 of the report, it says November 10, 2021, and that is the date that I signed it.

Q. So the work that you would have done to prepare this report, obviously, would have been work that was completed between October 18 when you were retained and November 10 when you wrote the report; fair to say?
A. Yes, sir.
Q. Of the 41 and a half hours that we looked at earlier from your billing through November 30th, how much of that time was spent prior to the preparation of your report?
A. I'm sorry. Are you asking about how the 40 hours were divided between different types of activities?
Q. Essentially, what I was asking you is: We know from the billing that you devoted 41 and a half hours of work to this assignment through November 30. Essentially, what I'm asking you is: How much of those -- what percentage or amount of those 41 and a half hours were spent prior to the time you prepared the report on October 10?
A. Got it. There were, I would say, three major categories of activities that the 40 hours were devoted to. One was reviewing the documents provided to me by counsel. The second was time spent meeting with counsel and discussing the case. And three is

time spent writing the report. For an allocation of those hours across these three groups of activities, I probably would say it's fair to think of that as, perhaps, one-third each; or, perhaps, half of the time devoted to writing and editing the report and the other half split evenly among reviewing materials and discussing with counsel.
Q. And am I correct that the materials that you reviewed as part of this assignment are include -- were included by you with your report?
A. I believe all of the materials that I relied on in writing this report has been cited and provided to you or is otherwise shared by you in your possession. They include Attachment B, which lists all of the papers and references. They include the complaint. They include other documents that counsel had provided me.
Q. Doctor, there's no question that you provided a list of documents that you reviewed and relied upon. As you mentioned, it's cited as Attachment B to the report that we've marked as Exhibit 4. Correct?
A. Yes, Exhibit 4 is my report and Attachment B is the right attachment.
Q. Yes. And what I was asking, perhaps

inartfully, was: Is there anything that you reviewed or relied upon or were provided with that is not listed in your report or on Attachment B to the report?
A. After my report was submitted, I had also, during a discussion with counsel, reviewed -- I had read other expert reports that counsel had sent me early in our discussions. They included a report by -- I want to make sure I recall these names correctly, but I may miss one or two -- but a report by Dr. Hecht, I believe, Dr. Lagana, I believe, Dr. Madigan, I believe, Dr. Etminan, I believe, Dr. Panigrahy, I believe. And if those were not all listed on Attachment B, they are -- they may have been submitted to you after my report as just an accounting of other documents in the case that I had reviewed.
Q. Did you review the reports from Hecht, Lagana, Madigan and Panigrahy before or after you wrote your report dated November 10th, 2021?
A. Largely before. I may have looked at them again after the report was submitted, but those were early documents provided to me by counsel well before I had begun drafting my own report.
Q. Okay. Let me ask you a couple of

questions about your background, if I might.
I understand that you received a Bachelor's Degree in Public Health Studies in 2006. Is that right?
A. Yes, from Johns Hopkins.
Q. And then in 2014, you received a medical degree. Correct?
A. Correct.
Q. And you also received a Ph.D. in Health Policy in 2012?
A. Correct.
Q. After you -- after you received your medical degree in 2014, you would have completed an internship in family medicine. Is that true?
A. No, sir, it was an internship and residency in total, a three year program in internal medicine, concentrating in primary care medicine at Massachusetts General Hospital.
Q. Should I call it primary care medicine instead of family medicine? Is that not the correct term these days?
A. Well, technically, it's the residency program in internal medicine. That's the overall name of the program; and we have a primary care track and a categorical track and I was a trainee in the

primary care track.
Q. Okay. We used to call them family doctors. We don't use that term anymore? I guess that's what I was getting at.
A. I see. Thanks for clarifying. Well, we could talk about this for a while longer, but family medicine still is a recognized specialty in the U.S. as is internal medicine and primary care. There are simply geographic differences in how the training programs across the country allocate training slots across family medicine and internal medicine and primary care.
Q. Where you were -- you received your -- you did your internship and residency at Mass General. Is that correct?
A. Massachusetts General Hospital, yes.
Q. Does Mass General have a separate internship and residency program for family medicine?
A. No, Mass General does not have a family medicine residency program.
Q. So if you wanted to practice what I call family medicine, you would perform your internship and residency in internal medicine with a focus on primary care?
A. Well, if you'd like to practice family

medicine, meaning that your practice includes pediatrics, adult medicine, geriatrics, then it would be most appropriate for you to enter a family medicine residency program. The residency program that I trained and focused on, adult medicine, specifically, adult internal medicine and not only primary care, but also primary care. So what I mean by that is, during my residency training, I spent a large portion of the time on the inpatient unit of the general medicine service as well as in the intensive care unit, in the cardiac intensive care unit, in the oncology inpatient unit, as well as in areas of subspecialty services, like, rheumatology and dermatology. And all the while doing that, I was a member of the primary care track, which meant that I had more time allocated to training in primary care, but it does not mean that primary care was the sole focus of my training.
Q. In any event, you completed your -- you would have completed your training sometime in 2017. Do I have that right?
A. Yes, residency spanned the summer of 2014 through the summer of 2017.
Q. And as far as your clinical practice today, your practice is in the field of adult primary

care?
A. I primarily practice adult primary care where I see patients in the outpatient clinic setting. However, roughly one month out of every calendar year I also practice inpatient medicine as an attending on the resident teaching teams on the inpatient units of the Mass General Hospital.
Q. And you've been practicing in your chosen field for about five years now?
A. If you define practice as starting after residency training, then, yes. You could also consider practice to be a part of residency training where we are acting as practicing physicians. So if you do the latter, then you would include the three years of residency training.
Q. Five years of post training practice. Can we agree on that?
A. Yes.
Q. All right. And you are not an oncologist. Is that correct?
A. Correct, I am not an oncologist.
Q. You do not practice pathology?
A. I am not a pathologist.
Q. And treating patients -- your clinical practice and the treating of patients, as I

understand, is just a small part of what you do on a day-to-day basis. Is that right?
A. I would disagree with that characterization, sir. First of all, I don't know what you mean by "small". As a primary care physician, I do engage in clinical thinking and clinical decision making every day. Even when I'm not in clinic, I often receive pages from patients, receive phone calls from my colleagues from clinic to help them answer a question, I receive lots of messages from our electronic medical records system to do prescription refills, answer patient questions, answer family questions, put in orders to keep care going, even when I'm not actively in a clinic session. I would consider all of that an active part of practice and when I'm physically in clinic in an active clinic session, I do that two sessions a week, about two half days a week, but there is a lot of work in the life of a primary care physician, a lot of clinical work that occurs outside of the clinic sessions.
Q. This week, starting with Monday, February 7th, 2022, how many hours will you see patients this week?
A. Given that this week has not yet ended,

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I cannot possibly tell you how many hours I will spend seeing patients. Who knows what will happen out there in the world in the future. But I was in clinic yesterday, my normal clinic hours for one session on a Monday where I spent roughly four, four and a half hours in direct patient care. Then I had follow up matters to do in the afternoon for my patients; filling prescription refill requests, answering patient questions, following up on test results that I had ordered in the morning, and writing letters to my patients to indicate what the results showed and providing guidance on their next steps. Those activities I typically do at night to wrap up the day. And today, thus far, I have not yet received a page, although, I probably have a few requests for prescription refills and questions waiting for me on the electronic medical records system, which I imagine I will attend to once we are finished here.

Q. Do you spend more time in clinical practice or doing teaching and research?

A. It depends on the week, it depends on the day.

Q. Okay. Have you ever testified that --

A. I can try to be more helpful, sir, but

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on average over, say an academic year or a calendar year, I spend more time doing research and teaching than I do in clinical practice. But I just wanted you to understand that there is variation day-to-day, week-to-week, month-to-month.

Q. Have you ever testified that you spend 80 percent of your time doing teaching and research and 20 percent of your time in clinical practice?

A. I have said that in many settings because, formally, as part of my academic appointment, I am what is typically called, and this is very common in academic medicine across the United States, an academic physician who spends roughly 80 percent of their time on research and teaching and 20 percent of their time on clinical care. That is the general divide that we all, in the academic medicine community, generally live by, as a matter of our formal appointment. That is not to say that in a typical day or week that's a precise allocation of hours.

Q. I'm not asking about a specific day or week at this point in time. I'm just asking generally, you know, in terms of overall allotment of your time, is that 80 to 20 apportionment accurate in your case?

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A. And I'm just trying to give you the most realistic answer, sir. In the long run, it's fairly accurate, yes.

Q. You testified that's the allocation of your time between research and testing and patient care; haven't you?

A. Well, as far as I recall, I have been asked about this in prior depositions and I've answered substantively the same. However, you've demonstrated a greater interest in this particular topic, and so I'm just giving you a more nuanced and precise and detailed answer. But 80/20 is our general academic versus clinical divide that, again, many, many of my colleagues in academic medicine and I generally follow.

Q. I'm more interested in honest answers than nuanced answers. Can I count on the prior testimony you've given under oath to be honest and truthful?

A. Absolutely.

Q. Okay. So you spend, on average, 80 percent of your time on teaching and research. Can you give me some examples of the current research programs that you're working on at present?

A. Sure. How detailed would you like me to

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be? How much would you like to hear?

Q. I just want to know generally what type of research you're working on?

A. Okay. Starting with the most general answer for you, I work on research pertaining to the health policy and health economics. To be a little more specific, pertaining to the determinants of healthcare spending, including prices of care pertaining to the measurement of provider quality and practice patterns and pertaining to disparities in health and healthcare.

Q. When you say "disparities in health and healthcare", what do you mean?

A. An example would be a recent publication in the peer reviewed journal JAMA health forum on December 23rd, 2021, which examined racial and ethnic disparities in hospitalization outcomes among Medicare beneficiaries in the U.S. attributable to the COVID 19 pandemic.

Q. And is that JAMA paper one that you published?

A. Yes, sir, I was the first author on that paper.

Q. And then when you talked about "research on the determinants of healthcare spending", what do

you mean by "determinants"?
A. Well, a very helpful framework we can keep in our minds is that healthcare spending is the product of prices of healthcare services times the quantities of healthcare services. And as a general policy matter, the growth of healthcare spending is important for public payors, private payors, employers and other entities in our society. And any policy that aims to address healthcare spending would need to either act on the price avenue or the quantity avenue because, again, price times quantity always equals spending. And therefore, my research has focused on the prices of care, some on the quantities of care, and a lot of work on efforts to address healthcare spending through payment reform and other policies that directly address spending.
Q. Is any of your research at the -- and the research you do is through the Department of Healthcare Policy at Harvard. Right?
A. Well, my primary appointment, my primary academic appointment is, yes, in the Department of Healthcare Policy at Harvard Medical School. However, I am also a teaching faculty at the Department of Medicine at Mass General where I do my clinical work as we have discussed; but also, where I

have worked with trainees on research papers, devised research questions that arise from our clinical work, and done research that you could plausibly argue was based at Mass General. So I have these two sites of employment.
Q. Has the development and establishment of treatment guidelines for cancer been the focus of any of your research?
A. As far as it pertains to my primary research in health policy and health economics, not so much.
Q. Are you familiar with the National Comprehensive Cancer Network or NCCN I think it's called?
A. By familiarity, if you mean have I heard of that, yes, I have. However, I would also note that as a primary care physician, I also reference and refer to guidelines from the United States Preventative Services Task Force, or USPSTF, and guidelines from the American Cancer Society, or ACS, and sometimes other guidelines as well.
Q. I appreciate that. I didn't ask about your tools that you use in your clinical practice just yet. All I asked is: If you're familiar with and heard of the National Comprehensive Cancer

Network; and I think you said you have.
A. I have heard of it.
Q. Have you ever served on an NCCN panel?
A. No, I have not.
Q. Have you ever contributed to the development of an NCCN treatment guideline for any cancer type?
A. I have not contributed to such development of guidelines.
Q. Have you ever published any research on the costs of cancer treatments specific to the cost of cancer treatment by cancer type?
A. That has not been the focus of my research.
Q. As I understand it, NCCN has published guidelines on colorectal screening. Is that true?
A. Did you say NCCN? You just cut out a bit there.
Q. Sorry. Yeah, I'll repeat the question. Has NCCN published guidelines on colorectal screening?
A. Like I was describing earlier, I believe NCCN, similar to USPSTF and the ACS, have put forth guidelines that we as primary care physicians know about; and therefore, to my knowledge, I believe they

have a guideline or a set of recommendations around colorectal cancer screening.
Q. Were you ever consulted or did you play any role in the development of the clinical practice guidelines for colorectal screening developed by NCCN?
A. No, sir.
Q. Have you ever published any peer review research on the cost of delivering care contemplated by NCCN guidelines for colorectal screening?
A. Specifically pertaining to colorectal cancer screening as published by NCCN, no, I have not.
Q. Let me ask you about lung cancer. Are you aware that NCCN has published clinical practice guidelines for lung cancer screening?
A. Again, I must say that lung cancer screening guidelines are put forth by many professional societies. I would argue prominently by the United States Preventative Services Task Force and the American Cancer Society and I would also expect the NCCN to have a set of recommendations or a guideline around lung cancer screening.
Q. Did you ever -- were you consulted or

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did you ever play any role in the development of clinical practice -- NCCN's clinical practice guidelines for lung cancer?
A. No, sir.
Q. Have you ever published any peer review research on the costs of delivering care contemplated by the lung cancer screening guidelines established by NCCN?
A. Specifically pertaining to lung cancer screening guidelines from NCCN, no, I have not.
Q. As part of your clinical practice, I assume you do not treat cancer. Correct?
A. Would you please define "treat".
Q. Well, that's a fair question. I'm not sure how I would define it. I mean, I've always assumed that oncologists treat cancer when a patient has been diagnosed. A primary care physician might manage the overall health of the patient while they're being under treatment. But I guess maybe the better question is: You tell me if you've got a patient that has been diagnosed with cancer, what role do you play in the care, if any?
A. My role as a primary care physician, and to be further helpful to you, sir, because I think I know where you're coming from, again, as I said

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earlier, I'm not an oncologist. And therefore, if you restrict the definition of "treat" to medical treatment, i.e. chemotherapy or other treatment modalities for cancer, i.e. radiation therapy or surgical oncology therapy, I do not practice those treatments because those are specialized treatments delivered by specialists. As a primary care physician, however, I do have patients who have had cancer in the past, who currently have cancer, and who may have cancer in the future. And counseling patients about cancer screening, reviewing their cancer's history with them, coordinating their care with their oncologists, understanding their care from their oncologists, and guiding them through their trajectory of care through the healthcare system in their chapters of life is what a primary care physician does and that's what I strive to do.
Q. Would I be correct in assuming that you do not have any expertise in determining the cause of cancer?
A. Would you please define "expertise"?
Q. Do you hold yourself out as an expert in determining the cause of cancer?
A. For the purposes of this case and specifically for what I was retained to opine on, the

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scope of my opinion certainly does not encompass that.
Q. Well, you're not an epidemiologist. Right?
A. Well, what do you define as an "epidemiologist"?
Q. Someone with a degree and specialized training in determining the cause of disease.
A. Well, first of all, I'm not sure I agree entirely with that definition of epidemiology.
Q. Well, you asked for my definition; didn't you?
A. I did, sir, yes.
Q. You got it.
A. I'm just reflecting -- I appreciate that. I'm just reflecting that an epidemiologist might challenge that definition. But I was trained as a health economist, specifically with the health policy Ph.D. degree and I would probably identify more closely with health economists or as a health economist than as an epidemiologist. Although, one could reasonably argue that some of my new research overlaps with the field of epidemiology.
Q. Have you ever been recognized as an expert in the field of epidemiology?

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A. Perhaps a student or someone in a course or a colleague or advisee may say that, but I would politely sort of decline that credit and just restrict my expertise to the letter of my training.
Q. Are you a toxicologist?
A. No, I'm not trained as a toxicologist.
Q. Do you intend to offer any opinions on cancer causation in this litigation, either generally or for any particular patient?
A. I have not been retained to opine on anything related to cancer causation in this case.
Q. And I take it that you will not be offering any opinions about causation in this case; fair to say?
MR. MIGLIACCIO: Objection. It's a vague question, but you can answer.
THE WITNESS: Based on everything I have learned to date, my understanding is that my role as an expert witness in this case is -- does not include opining on cancer causation.

BY MR. TRISCHLER:
Q. You -- in reading your report that we marked as Exhibit No. 4, it appears to me that you have assumed the existence of a definable class of

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individuals with a lifetime cumulative exposure to NDMA or NDEA that is sufficient to create an increased risk of cancer. Right?

MR. MIGLIACCIO: I'm going to object to the extent that it calls for a legal conclusion, but you can answer.

THE WITNESS: Would you please elaborate on what you mean by "assume"?

BY MR. TRISCHLER:

Q. Well, just that. Webster's text book definition of assume. For purposes of your report and your work in this case, you've assumed that there is a definable class of individuals who have a lifetime cumulative exposure to NDMA or NDEA that's sufficient to create an increased risk of cancer. Right? That's something that you've assumed and then you're going to monetize a monitoring program for that group or class of patients. Right?

A. I just want to be very specific and precise here. The scope of my work in this case pertains to the pricing of medical services for a potential monitoring program for a potential certifiable class of individuals. My report illustrates how a common methodology can be derived

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and applied to determining the prices of medical services for a potential medical monitoring program. To my knowledge, such a monitoring program has yet to be certified. To my knowledge, such a monitoring program -- such a class has yet to be certified. So in the absence of that, I am illustrating how the common methodology for the pricing of medical services works and providing you a lot of information about the pricing of medical services in general in the U.S.; but I want to be specific about your use of assuming with what I've just stated now.

Q. Will you be offering any opinion on what lifetime cumulative exposure levels create an increased risk of cancer?

A. That is outside the scope of what I was asked to opine on in this case.

Q. Do you know whether there is any -- whether there are any individuals who have a lifetime cumulative exposure to NDMA or NDEA that's sufficient to create an increased risk of cancer?

A. Again, that question is well outside of the scope of what I was asked to opine on in this case.

Q. All right. You said it was outside the scope of what you were asked to opine on. The answer

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is you don't know. Right?

A. That's an incorrect characterization. What I would say is that, to my knowledge and reading the documents that we discussed earlier that were provided to me by counsel as part of this case, I understand that there is a scoring system for determining exposure to these carcinogens. So it's not that I don't know anything about the subject matter that you're asking about, but I do want to emphasize that that question is outside the scope of what I was asked to opine on for this case.

Q. How many individuals in America have a lifetime cumulative exposure to NDMA or NDEA sufficient to create an increased risk of cancer? Do you have any idea?

A. That is well outside the scope of my work and my report in this case.

Q. Because it's outside the scope of your work, you don't have any idea what that number is; could be zero, could be 100, could be some other number. Right?

MR. MIGLIACCIO: Objection. Compound. Misstates.

THE WITNESS: Again, your characterization of my thoughts is not something that

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I would agree with, exactly. I have not fully considered or investigated or researched or thought through a question like that. So at the moment, in the context of my report, which you have in front of you, it is outside the scope of my work in this case.

BY MR. TRISCHLER:

Q. So is it fair to say that your opinion goes only to whether there is a common method to calculate the cost to fund a medical monitoring program, if one's deemed necessary and appropriate down the road?

A. Maybe I could restate that in a somewhat similar fashion. The scope of my work as an expert witness in this case pertains to the pricing of medical services in a potential medical monitoring program. The scope of my report also includes many underlying facts and discussion of issues around the pricing of medical services, which are germane to the main thesis of my report, which is development and discussion of a common methodology for the pricing of medical services in the U.S. healthcare system.

Q. And that's what you -- that was what -- for some reason I think you like to restate what I say and expound upon it. But my question was: What

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you've opined and articulated or what you hope to opine or articulate is that there is a common method for pricing medical services among whatever individuals are determined to be part of this class, if one should ever be certified. Right?

A. A common methodology for pricing medical services, yes, I would agree with that brief summary you just provided.

Q. So in Paragraph 7 of your report, and it's in the chat so you can feel free to pull it up if you need to.

A. Thank you.

Q. Paragraph 7 of your report, you write that Plaintiffs propose a "medical monitoring class is defined as all persons who consumed the Defendants (VCDs) Valsartan-containing drugs, containing NDMA or NDEA, and who accumulated sufficient quantities of lifetime cumulative exposure to require medical monitoring given the increased risk of cellular and genetic injury leading to an increased risk of cancer."

Did I read all that correctly?

A. I believe so, yes.

Q. That sentence appears at Page 4 of your report that we've now highlighted. Correct?

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A. Correct.

Q. When you refer to an increased risk of cancer in your report, to which types of cancer are you referring?

A. Although the specific types of cancers were outside of the scope of my work in this case, to my understanding in reading the materials provided by counsel that we discussed earlier, my recollection is that the types of cancers that individuals who have consumed a sufficient quantity of these carcinogens would be at risk for include cancers such as; colorectal cancer, lung cancer, and a number of others.

Q. Well, how many others?

A. Recalling off the top of my head, based on my recollection of those other documents in the case, several additional types of cancers. I believe also including breast cancer is one of the additional types.

MR. TISCHLER: Let's take a short break.

THE VIDEOGRAPHER: The time is 10:28. This ends media unit No. 1 and we're going off the record.

(Whereupon, a brief recess was taken off the record.)

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THE VIDEOGRAPHER: The time is 10:40. This begins media unit No. 2 and we're back on the record.

THE WITNESS: I just want to revise my recollection from my last response to your question. Right after we went off the record, I thought about your question for a second more and I recollected that breast cancer is actually not, as far as I recall, one of the other cancers in that list that you had asked me about. But I also remembered esophageal cancer and stomach cancer, pancreatic cancer is several other examples that you had asked about. So I just wanted to make that revision to my recollection just now. Thank you.

MR. TRISCHLER: Sure.

BY MR. TRISCHLER:

Q. After we took a break, you had a chance to go into a little breakout room with Plaintiffs' counsel. Did they help you refresh your recollection on that?

A. Not at all. I literally thought about it in the first couple of seconds we were off the

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record and I better remembered based on my prior reading of the case materials.

Q. Good. So now that you better remember, are you aware of the fact that the plaintiffs in this litigation are alleging that members of this proposed class face an increased risk of nine different cancers?

A. As I just provided you, I think, four or five examples, there is a list of cancers at which exposure to these carcinogens and Valsartan-containing drugs puts an individual at a higher risk of -- nine sounds correct, but I would just refer back to the earlier case documents to verify that.

Q. Well, now just to be clear, I'm not interested in what you read from others because you told me that you've been provided the expert reports from Plaintiffs' expert witnesses and you reviewed those both before and after your report. Right?

A. Well, this question you're asking about was not -- was not the substance of what I was retained to opine on. So, yes, I read those additional documents both before and after writing my report. But because it wasn't central to the question that I was asked to address, I'm just

letting you know that I'm producing for you what I recall from off the top of my head and if you ask me a specific number of items on a specific list, I'm kindly requesting that we simply refer back to that document, which you have in your possession. So nine sounds about right, that's what I recall from reading.

Q. Well, I'll get back to the cancer types in a minute. I'm trying to ask you something different now. I'm trying. You were provided with expert reports from retained experts by the plaintiffs in this litigation. Correct?

A. The reports that I had earlier listed for you, those are the reports that I was provided.

Q. You've not done any independent research on the carcinogenicity of nitrosamines; have you?

A. The carcinogenicity of nitrosamines was well outside of the scope of what I was retained to opine on in this case.

Q. So the answer is, you've not done any independent research on the carcinogenicity of nitrosamines. Correct?

A. Well, your definition of research might differ from mine. I don't want to try to read your mind by what you exactly mean by "research". (Two

people talking at the same time.)

Q. Well, then let me ask another question, sir, because it's going to be a long day if you don't want to answer direct questions.

Aside from reading -- aside from reading expert reports from Plaintiffs' experts that were spoon fed to you by the Plaintiffs' lawyers, have you done any other independent research on the carcinogenicity of nitrosamines?

MR. MIGLIACCIO: Objection to the form of the question. You can answer.

THE WITNESS: Just to be fair, sir, I am trying to answer all of your questions directly and it's actually in my effort to answer precisely and with the appropriate nuance that I think your reaction is getting at. So to restate in a different way, perhaps, the carcinogenicity of nitrosamines is well outside of the scope of my expert report and my work in this case. I, through reading the documents pertaining to this case, certainly read about the carcinogenicity of nitrosamines, but it is the same information that you have at your disposal, as I did, in what I was given.

BY MR. TISCHLER:

Q. Okay. Let's see if we get a nuanced answer or a straight answer that actually answers the question. Other than reading expert reports that were given to you by the Plaintiffs' lawyers, have you done any other independent research on the carcinogenicity of nitrosamine?

MR. MIGLIACCIO: Objection to the form of the question.

THE WITNESS: Independent original research done by myself as a researcher, no.

BY MR. TRISCHLER:

Q. So you mentioned some of the cancer types that you understand to be at issue in this case and I jotted them down. You mentioned colorectal cancer, lung cancer, pancreatic cancer, esophageal cancer, stomach cancer. Correct?

A. Yes, thank you for writing those down. I believe those were the five examples I recalled off the top of my head for you, both before and after the break just now.

Q. And since you had a chance to remember better during the break, my question is: Do you remember what the other four cancers that Plaintiffs claim could be at issue in this case?

A. I can try, sir. To the best of my recollection at the moment and, again, emphasizing that this is unrelated to the pricing of medical services and quite far afield from what I was asked to opine on, I believe another member of that list of nine you're referring to would be blood cancers or what we in medicine call a hematologic malignancies. And so, if you agree with me that there are three more on your list, I would just kindly request that -- unless you would like to force me to keep thinking about the three, I would stop my recollection there.

Q. So those six are the only ones you can remember, sitting here right now?

A. At this moment, with the way you're asking me, those are the ones that I recall.

Q. Well, if I ask the question in a different way, would it help you recall what the other three are?

A. I need to answer all of your questions respectfully, sir, but if in your question you provided me the answer, then certainly I would be able to recall.

Q. Okay. Well, how about bladder, prostate and liver, do they ring a bell?

A. Okay. So you just provided to me the other three in your question and, therefore, I can confirm that they too ring a bell.
Q. To monetize a monitoring program to adequately screen for multiple cancer types, don't you agree that you need to know the cancer types at issue?
MR. MIGLIACCIO: Objection. Misstates.
THE WITNESS: I disagree with the framing and connotation of your question, actually, sir. As I noted just a moment ago, the pricing of medical services is unrelated to the clinical substance of what you're asking about. As I clearly stated in my report, every medical service in the United States has a common procedural terminology or CPT code. That code designates the service, that code is attached to prices we can talk about, prices in public and private aspects of our healthcare system. But the pricing of medical services is unrelated, uncorrelated with the substance of your question just now. And furthermore, it's outside the scope of my report, which is to propose a common methodology for pricing medical services.
Q. That's as confusing as can be to me because you've sat here and suggested that there

exists a common methodology that can be utilized to determine the cost to fund a monitoring program. Right?
A. A common methodology for the pricing of medical services, right.
Q. But as we sit here right now, we don't know how many people will be in that program, how many patients. Right?
A. Let me --
Q. Do we know how many -- do we know -- no, answer my -- sir, the way the deposition works is you're supposed to answer my question. My question: Do we know how many people are going to be in the hypothetical program?
A. I respect you and I understand your question and I am honestly providing you the best answer that I can.
Q. How about a "yes" or "no"; do we know how many people will be in this program?
A. Not only is that outside the scope of what I was asked to opine on in this case, which is the pricing of medical services in the U.S. healthcare system that, to my knowledge, has also yet to be finalized or certified in this case.
Q. So we don't know how many people will be

part of the program. Right?
A. Well, as a general matter, sir, if you ask me about something that has not been finalized or certified, then in my position as an expert witness and also not being a lawyer in this case, I, of course, cannot purport to give you an answer on something that has not been finalized and certified. And all of this, again, is outside the scope of what my report is focused on, which is -- (two people talking).
Q. Do we know how many people -- do we know how many people in this -- do we know how many people in this program are Medicare recipients?
A. It follows from what I just said that if a final class of individuals has not been determined and certified, then it would not be possible for us to know the exact break down of such a population along dimensions of characteristics, including payor mix.
Q. And we don't -- and do we know what services will be included as part of this hypothetical program?
A. Also very consistent with something I responded to you earlier about the components of a proposed medical monitoring program have not been

finalized and certified, to my knowledge, in this case, at the moment. So you are asking me about what is a final certified set of services in a monitoring program and my best answer for you is that, to my knowledge, that finalization of certification has not yet taken place.
Q. And we don't know how many people in this program will have private insurance. Correct?
A. I believe I've answered this question because you just asked about Medicare. My answer for you would be analogous. In fact, I think something that would actually help both of us in this current discussion is what I mentioned earlier this morning, which is the potential spending of a potential medical monitoring program is the prices of the services in that program multiplied by the quantities of those services rendered. And the quantities of those services rendered, which you're focusing on now, breaks down into how many times those services are done and how many people are in that class. Because the exact services and the exact class have not been finalized and certified, my report focuses on the pricing of medical services. Price times quantity equals spending. My report focuses on pricing. I just explained to you two dimensions of

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quantities that are important, but not yet finalized and certified. When you multiply those together, you get estimated spending for a monitoring program. So I want to be precise. If you ask me about prices, which is germane to my report, I'm happy to answer any questions you have. If you ask me about the quantities of services rendered and who are they going to be rendered on, those aspects have not been finalized and certified yet, to my knowledge.

Q. Do we know how many private health insurers are part of this program?

A. Again, that's an element of the quantities of services eventually rendered that has not yet been certified and finalized.

Q. Do we know how many uninsured individuals are part of this program?

A. Again, that's an element of quantities which has not been finalized and certified; and, furthermore, not the focus of what I was retained to opine on in this case, which is what pertains to the pricing of medical services.

Q. And do we know what services are to be provided for each of the nine different cancer types that are part of this global program that's been proposed?

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A. I believe I just answered that. The quantities of services, which you're precisely asking about here, has not been determined and finalized. And, again, price times quantity equals spending. My report focuses on the pricing of medical services. The quantities aspect has not been finalized and certified. And all your questions or previous questions here are regarding quantities; and so I'm not able to speak to aspects of the case that have not been finalized and certified. Price times quantity equals spending and that's a framework that will always hold true. We can use that as a launching point for your questions.

Q. In your work in this case, have you seen any epidemiological study suggesting or concluding that exogenous intake of NDMA or NDEA is a cause of colorectal cancer in humans?

A. Similar to how you asked me previously about the carcinogenicity of nitrosamines, I had answered already that I did not do independent investigative research into that question. It seems to me that you're asking about that again. So my answer would be the same as earlier, that is outside the scope of what I was retained to opine on in the report. In fact, well outside the scope. That does

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not even pertain to price times quantity equals spending. And also, it's something that we've already addressed.

Q. So are you able to cite an epidemiological study suggesting that exogenous intake of NDMA or NDEA leads to or causes colorectal cancer in humans; yes or no?

A. Cite connotes independent research; does it not? And if it does, I have already answered that I have not done my own independent research on that question, which falls well outside the scope of what I was asked to opine on in this case, sir.

Q. Are you aware of any study, any epidemiological study concluding that exogenous intake of NDMA or NDEA causes lung cancer in humans?

A. I'm going to try to be more helpful for you, sir, because I think repeating my answers, you know, you've already expressed your displeasure at that. So let me just state this, this way.

Q. I'm not expressed any displeasure about anything, sir. I'm looking for straightforward, yes or no, truthful answers to questions.

A. No, I appreciate that and I --

Q. No, please don't -- hold on. Hold on. Please don't interrupt me and please don't

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characterize my view. I'm asking questions. I'm entitled to answers to them. You're not entitled to characterize my thought process.

A. And I'm trying my best to give you the best answers to my knowledge and my ability. So the way I was going to try to give you more helpful answers for you is that, as a general clinical matter, I think it's fair to characterize as common knowledge that NDMA and NDEA are potential carcinogens to human beings. And, therefore, if it is common medical knowledge and you could debate how common it is among physicians of different specialties, but if we take for the moment that it is fairly common medical knowledge, then there must be studies, there must be peer reviewed literature supporting such common knowledge in medicine, as there would be for any clinical conditions that we think about and treat on a day-to-day basis. So, you know, I'm trying to be more helpful to you because, through that angle, I can say that I would expect there to be citable peer reviewed academic studies that address the relationship between NDMA and NDEA and carcinogenicity. But again, whether -- did I undertake that original research myself in this case as part of my work? There I have repeatedly told you

that it's well outside the scope of what I was asked to do.

Q. Do you even remember what my question was, sir?

A. Yes.

Q. My question was: Can you cite an epidemiological study suggesting or concluding that exogenous exposure to NDMA or NDEA causes lung cancer in humans? I'm not looking for you to say you think there is. Can you cite it? If so, tell me what the cite is.

A. Thank you for repeating that question. Because I did not independently undertake such research investigation, given that it was well outside the scope of what I was asked to opine on, I do not have a citation to provide to you off the top of my head at this moment.

Q. Can you cite any epidemiological study published anywhere in the world concluding that exogenous exposure to NDMA or NDEA causes any of the nine cancer types in humans that are alleged to be at issue in this litigation?

A. I would offer the same response I just gave you before. If you want me to elaborate, I can, but I'll pause here.

Q. I want you to answer the question. Can you cite any literature?

A. Okay. Because I did not undertake this original research investigation of the evidence underlying carcinogenicity, which is what you're describing in your question, as I've noted before multiple times, given that it was outside the scope of my work in this case, I'm not able to provide you a citation off the top of my head because it is very unrelated to the subject matter of my report.

Q. Nevertheless, while you cannot cite a single study establishing that exogenous NDMA or NDEA exposure causes any of these cancers in humans, it's your opinion that every class member should be screened for all nine of these cancer types. Right?

MR. MIGLIACCIO: Objection. Compound. Vague.

THE WITNESS: I disagree with your question in a couple of very important ways. So if you will, please give me a little bit of time to explain.

No. 1, it is not that I cannot provide a citation for what you're asking about. It is that my scope of work in this case as an expert witness is far afield from this question. And because I believe

such citations must exist out there in the medical literature, given this is fairly common clinical knowledge, if afforded the time and opportunity to do some of this initial original research investigation, I'm sure that I could provide for you more than one citation to your liking on that question. And the second -- (two people talking).

BY MR. TRISCHLER:

Q. If you did, you'd be the first.

A. Excuse me, sir. Please let me finish.

Q. If you did, you'd be the first.

A. Please, let me finish my answer, sir. The second area where I must disagree with your question is that, as I'm sure you know, I'm not the only expert retained for the Plaintiffs and you've already established that I'm not an oncologist, you've already established that I'm not a toxicologist and you're asking questions germane to oncology and toxicology. So your questions are outside of the scope of my expertise that you've already helped me define. And furthermore, you have at your disposal, I believe, Dr. Kaplan, who is an oncologist, who would be, presumably in a much better position to answer that question for you relative to

me as a primary care physician and health economist.

Q. So is it your testimony that it's outside your expertise to define what screening procedure should be employed for stomach cancer?

A. It is certainly outside the scope of what I was asked to opine on in this case.

Q. That wasn't my question. My question is: You just said it was outside the scope of your expertise, I think. So I'm asking you to clarify. Are you suggesting that it's outside the scope of your expertise to define the procedures that should be included in the screening program designed to detect stomach cancer?

A. For the purposes of this case and specifically for my report, sir, which I think is the focus of our discussion today, my expertise pertains to the pricing of medical services. I do work as a physician, as you've already established. I do see patients and have expertise in clinical medicine before I would -- but for what I was asked to opine on in this case, your question, unfortunately, is far afield of that. And I respect the importance of this matter, this litigation, and I respect the other parties involved here including another expert like Dr. Kaplan, so I want to appropriately address your

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1 questions within the scope of what I was asked to do.
2 Q. Do you have the expertise to establish
3 the procedures that should be employed to detect
4 stomach cancer? Yes or no.
5 MR. MIGLIACCIO: Objection. Asked and
6 answered.
7 MR. TRISCHLER: No, it wasn't. It was
8 asked. It wasn't answered. He said it was outside
9 the scope of his report. That wasn't the question.
10 My question is: Does he have the expertise to do it?
11 That question has not been answered. For some reason
12 he seems to want to avoid answering it and many
13 others.
14 THE WITNESS: In an effort, again, to be
15 precise, for the purposes of my work in this case and
16 the report in front of you, that is outside of my
17 purported expert opinion, my proposed expert opinion
18 for you.
19
20 BY MR. TRISCHLER:
21 Q. I know it's -- you've said that. My
22 question is: Is it outside your expertise?
23 A. And I've also said that I certainly have
24 expertise in clinical medicine outside of my work in
25 this report, but that expertise is not germane to my

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1 work in this report or in the scope of what I'm doing
2 or what I was retained to do by counsel. So again,
3 out of respect to the other parties in this case,
4 including counsel, including the other Plaintiffs'
5 experts, I want to just be very precise with you
6 about what I'm doing in my report, which is the
7 pricing of medical services and I would invite you
8 and would be happy to answer any of your questions
9 regarding my report.
10 Q. I didn't ask you what you did in your
11 report. Do you understand that? I asked you: Are
12 you an expert in formulating the protocols and test
13 procedures and test methods that one should employ in
14 developing a screening program for stomach cancer?
15 It's a different question entirely. Tell me.
16 A. Thank you, sir. That's actually a
17 different question entirely than the questions you
18 asked earlier, so I appreciate that. I am not an
19 expert in the formulation of the derivation of
20 original clinical guidelines for cancer screening
21 because no single physician is. Those are
22 professional society guidelines put forth by, you've
23 already said this earlier, the National Comprehensive
24 Cancer Network, NCCN, the American Cancer Society,
25 the United States Preventative Services Task Force.

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1 Those are not individual physician jobs. Those are
2 professional society guidelines, so neither me nor
3 any other individual physician sitting here, would be
4 nor should be able to say to you that they are the
5 originator of such guidelines.
6 Q. I didn't ask you that question either,
7 but I'm used to it by this point in time.
8 What screening and detection methods
9 would you use for stomach cancer?
10 MR. MIGLIACCIO: Objection. Vague
11 question.
12 THE WITNESS: Would you mind specifying
13 for what patient?
14
15 BY MR. TRISCHLER:
16 Q. Well, is it patient dependent?
17 A. Well, if you're going to ask me how I
18 make a clinical judgment, how I make a clinical
19 judgment about services for patients, without
20 providing me any specificity about the patient or
21 patient population you're thinking of, I think that's
22 an unfair question. Even in the clinical guidelines,
23 as you know, sir, sorry, I'll finish very quickly,
24 even in clinical guidelines, I'm sure you're well
25 aware that in the specific recommendation statements

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1 included are characteristics of the patient
2 population to be screened, whether they're average
3 risk, whether they're high risk, whether they've been
4 exposed to a carcinogen like tobacco or whether they
5 have a family history. So without providing me any
6 specifics, and I know you're getting at individual
7 physician differences -- individual patient
8 differences here in your question, but without
9 providing me any specifics about the patients you're
10 thinking of in your mind, that question, frankly, is
11 clinically inappropriate.
12 Q. So in order to answer the question of
13 what screening and detection methods you would use to
14 try and detect stomach cancer, you need to know about
15 the patient and the patient history?
16 A. Well, you may not need to give me
17 everything about a patient, every characteristic, but
18 at least something. What age group are you thinking
19 of? What exposure to NDMA or NDEA do you have in
20 mind? You know, I think those are fair questions in
21 the context of this case for me to answer a clinical
22 question like that.
23 Q. What -- well, the screening and
24 detection methods that you use to detect stomach
25 cancer differ from the screening methods for liver

cancer?
A. In the context of this case, and this is a good question, I would defer to the expert opinion of oncologists like, potentially, Dr. Kaplan to answer a question like that. As a primary care physician, I follow guidelines and the recommendations of my specialist colleagues and so I would, again, for pricing of medical services, apply the common methodology for pricing to whatever the services that are certified and finalized end up being.
Q. Well, it's interesting -- it's interesting that you say you follow guidelines, what published guidelines are there for screening of liver cancer?
A. Well, again, it depends on which patient population you're thinking of. I'll just give you one concrete example to answer your question and I hope it drives home the point. Okay? For patients with cirrhosis, commonly due to alcohol or due to fatty liver disease or due to hepatitis, of which there are several types. Patients with cirrhosis are recommended to receive screening for hepatocellular cancer, HCC, that is a type of cancer of the liver which deserves screening under certain clinical

conditions. Okay. So that is an example of a clinical thought process that requires some detail from the questioner's standpoint if you want a precise clinical answer.
Q. So patient medical history can dictate what screening and detection procedures are done in a given case?
A. To an extent.
Q. And you didn't answer my question as to what guidelines exist for screening, what published guidelines exist for screening. You said there were recommendations on liver screening for patients diagnosed with cirrhosis, but what published guidelines are there?
A. Right. I believe I just answered that for you by giving you a very concrete example. If you look at the -- of course, this was not part of my work in this report and this is off the top of my head as a primary care clinician. And I would, again, refer you to Dr. Kaplan for a primary opinion on this, but if you look at the guidelines from the gastroenterologies societies, especially the hepatology societies, they would clearly state for you that a patient with A, B or C, pertaining to liver disease, should receive liver screening using

ultrasound or CT or other modalities at a frequency of X or Y. That would be the sort of recommendation or the format of a recommendation you would commonly see. And in my residency training a number of years ago, I can recall learning those guidelines. So I'm fairly confident sitting here today that they do exist. But, again, I want to emphasize this is very far afield, sir, from the pricing of medical services. And I also noted earlier that pricing of medical services in the U.S. is unrelated to these clinical nuanced differences between patients and that's an important point to establish here. The price of a CPT code of a service is derived from a common methodology, which is unrelated to these differences across patients that you are exploring here with me.
Q. Would you agree with me that screening and detection methods for colorectal cancer differ from, like, screening and detection methods you might employ if you were looking for pancreatic cancer?
MR. MIGLIACCIO: Objection. Vague. Incomplete hypothetical.
THE WITNESS: I do agree that's a vague question, but I will try to help out the question in this way. Screening for colorectal cancer involves,

among other things, colonoscopies. Colonoscopies are not used to screen for pancreatic cancer. With those two facts just given to you, the answer to your question is, yes, there are differences in how doctors in America screen for colorectal cancer relative to how they screen for pancreatic cancer.

BY MR. TRISCHLER:
Q. And have you ever designed or implemented a screening or detection procedure for asymptomatic patients to screen for pancreatic cancer?
A. There are two parts of your question; one is about designing such screening procedures and another is the implementing such screening procedures. So to break them down, again, consistent with my prior answers, I have not designed screening procedures for pancreatic cancer or screening procedures for any other cancer because, again, they come from large professional society guidelines constructed by a large consortium or committee of experts in those fields. With regard to the second part of your question which is around implementation, pancreatic cancer is something we think about in primary care, but unlike other cancers, such as

colorectal cancer and lung cancer, there are fewer options for screening for pancreatic cancer.

Q. So if I understand your report and the testimony that I've heard from you so far today, at this stage of the proceedings, you've made no attempt to monetize the cost for services for global colorectal screening for all patients in this proposed class. Right?

MR. MIGLIACCIO: Objection. Misstates.

THE WITNESS: I really have to offer you an answer that breaks your question into pieces again because there are a few things in there that I don't -- I don't believe we're on the same page on. One is the pricing of medical services, I don't want to get too technical, but it is different from the, in your words, monetizing of costs. I've established that pricing is synonymous with monetizing, so I'm able to work with you on that synonym there --

Q. That synonym comes from you.

A. Yeah, yeah, pricing --

Q. I didn't make it up. It came from your retention agreement and what you said you were going to do.

MR. MIGLIACCIO: Objection. Misstates.

THE WITNESS: Sir, I'm simply

reaffirming that the pricing of medical services is --

BY MR. TRISCHLER:

Q. Well, don't say it's my term, sir.

A. You just used it in your question, that's all I'm referring to. So the term in your question, monetizing of costs and the phrase that I've used consistently with you today, the pricing of medical services, I just want to be specific and precise about this. I'm willing to let us use pricing to mean monetizing in your -- the word you use in your question. When you refer to costs, as I noted in one of the paragraphs of my report, I just want to make a distinction between costs and spending. Spending is price times quantity. Okay? When we estimate the spending of something in healthcare, when we estimate healthcare spending, when we study healthcare spending, when we write about healthcare spending, spending is prices times quantity. That is the substance of what you're asking me about here.

Costs, when you use the word "cost", as I noted in my report from a technical academic standpoint, which is the world I live in, costs refer

to the underlying costs of production of a medical service. Okay? You're connoting spending but I'm going to use the word spending to be precise. Would you mind repeating the second part of your question? It just slipped --

Q. Well, I'm sure it won't be -- the response won't be responsive anyway, but can you read it back, please, Jomanna?

(Whereupon, the requested portion of the record was read by the reporter.)

THE WITNESS: Thank you for repeating that. The second part of my response was that because the members of this class have not been finalized and certified, I don't know who they are at this time. And therefore, when you say "global for all members of this class", given that this class has not yet been certified, I'm not able to provide you specific clinical answers or economic answers about pricing related to a class that has not yet been certified.

BY MR. TRISCHLER:

Q. And for the vast majority of the cancer

types at issue in this case, can we agree that there's no universally recognized screening or detection guidelines?

MR. MIGLIACCIO: Objection. Again, vague question.

THE WITNESS: Again, that falls well beyond the scope of my report. You're asking for a clinical judgment here and my opinion is not in that domain for what I was retained to opine on. I want to be helpful to you; as a primary care physician, I do think -- I do think about cancer screening. If you want to reformulate your question or perhaps be a little more specific, I might be happy to try to answer your questions.

MR. TRISCHLER: I really don't want to reformulate it. I'd like an answer to it.

BY MR. TRISCHLER:

Q. Are there established guidelines for the detection and screening of esophageal cancers; yes or no?

MR. MIGLIACCIO: Objection. Vague. Incomplete hypothetical.

THE WITNESS: It depends what patients you're asking about. As a primary care physician,

that is my best answer for you. You would need to provide me a little more specifics about the patient population you're thinking about in your mind.

Q. The patient population of Valsartan users.

A. To my knowledge, there exist no guidelines recommended by large professional bodies pertaining to patients who have used Valsartan, specifically for the screening of esophageal cancer. To my knowledge, such guidelines don't exist today. So if you're asking me about those guidelines, that would be my best answer.

Q. Well, what guidelines do exist for the screening of esophageal cancer?

A. Okay. Again, I'm going to try to be helpful, sir. And this is outside the scope of what I've been retained to opine on in this report. As a primary care physician, I will say as a general clinical matter for patients at higher risk of developing esophageal cancer, there are clinical services that our specialty colleagues, like gastroenterologists and oncologists may recommend for the screening of esophageal cancer. One such service would be an endoscopy, but it, again, depends on the specific population of high risk patients that you

are thinking about.

Q. I'm asking you about guidelines that have been published by USPSTF or NCCN for screening and detection of cancer in asymptomatic patients. Have any organizations responsible for developing treatment guidelines, such as NCCN or USPSTF ever published any guidelines for the screening of esophageal cancer?

MR. MIGLIACCIO: Objection. Asked and answered.

THE WITNESS: And it's well outside the scope of my opinion in this case. At the moment, sitting here, off the top of my head, I'm not able to replicate for you any such guidelines.

BY MR. TRISCHLER:

Q. Does an inability to replicate mean that there are none?

A. Again, I've just explained that for high risk individuals, we as generalists sometimes receive recommendations from specialists to screen for esophageal cancers with an endoscopy, but again, this is highly hypothetical. Your question is unconnected to Valsartan now, specifically and I would refer you to --

Q. Sir, your job -- your job is to answer my questions, not to argue with whether they're outside the scope, whether they're hypothetical. Your job is to answer them. If there are objections to be made, your counsel will make them and the court will rule on them later, at some point in time. I'm entitled to answers to my questions and I would like them.

Does NCCN or USPSTF have any published guidelines recommending screening procedures for asymptomatic patients to detect esophageal cancers; yes or no?

MR. MIGLIACCIO: I object. First, you've asked that question and he's answered it. He's giving you his best answers. And you're being argumentative at this point. I think he's doing his level best to give you his best answers here.

MR. TRISCHLER: That speaking objection is improper under the rules established by this court and under the federal civil procedures. Please refrain from it.

MR. MIGLIACCIO: I'll refrain from those speaking objections if you refrain from characterizing his answers as being evasive or that he's not answering questions because he is.

MR. TRISCHLER: Are you done?

MR. MIGLIACCIO: I'll be done when you're done.

MR. TRISCHLER: I'm waiting for an answer to the question.

THE WITNESS: Okay. Again, let me try to be helpful, sir. First, I want to reaffirm that I respect your role in our discussion here.

BY MR. TRISCHLER:

Q. You don't have to do that. You just have to answer my question, sir.

A. And that is part of my answer, sir. That's an appropriate preface to my answer for you.

Q. Actually, it's not because it's nonresponsive. I don't need you to -- I don't need you to preface every answer with a comment. Just answer the question.

MR. MIGLIACCIO: Objection to your commentary.

THE WITNESS: My preface was only a result of your reaction, let me just put that there. As a general clinical matter and speaking as a primary care physician, again, not as an oncologist as you've already established, I don't recall off the

top of my head right now guidelines for asymptomatic -- what was it you said in your question? This is why the clinical detail is important here. I'm trying to recall. You said asymptomatic individuals screening for esophageal cancer and you're asking about guidelines published by the USPSTF or the NCCN or, perhaps, the American Cancer Society. If that's a fair summary of your question, and my answer to you is: A) I would refer to our oncologist expert who would be much better positioned to answer that for you; and B) as a primary care physician, I don't recall as a general clinical issue off the top of my head such guidelines; and C), most importantly, this falls well outside of the scope of what I was asked to opine on in this case.

BY MR. TRISCHLER:

Q. Are there any guidelines that have been published by NCCN, USPSTF or the American Cancer Society recommending screening for bladder cancers in asymptomatic patients?

MR. MIGLIACCIO: Objection. Vague. Incomplete hypothetical.

MR. TRISCHLER: Well, there are either

guidelines or there are not. That's a meritless objection.

THE WITNESS: Can you provide any helpful clinical detail outside of asymptomatic, sir?

BY MR. TRISCHLER:

Q. No.

A. Okay. In the absence of any further clinical detail that you can provide, the best answer I can give you is, as a primary care physician and not an oncologist, I do not recall off the top of my head at this moment any such guidelines or what such guidelines say.

Q. Are you aware whether any guidelines have been published by USPSTF, NCCN or the American Cancer Society recommending screening for pancreatic cancers in asymptomatic individuals?

MR. MIGLIACCIO: Same objection.

THE WITNESS: And my same response to you, sir. I would just also add, again --

BY MR. TRISCHLER:

Q. I don't know what that same response means.

A. Okay. Let me try to replicate that --

Q. You're either aware, Doctor, of the existence of guidelines or you're not.

A. I've already established for you in an earlier answer that relative to, like, colorectal screening, there are fewer modalities, fewer options we have in clinical medicine as a general clinical matter for screening for pancreatic cancer. I've already offered you that answer, which is, again, unrelated to my expert work in this report. I'm trying to be, now, further helpful and say that as a primary care physician and not as an oncologist, I cannot recall off the top of my head sitting here right now what such guidelines are or what they say regarding asymptomatic individuals for working at a cancer outside of what I just repeated for you from that earlier answer. And, again, I must emphasize how distinct and unrelated this is to the subject matter of what I was retained to opine on in this case.

Q. Are you aware of any guidelines published by USPSTF, NCCN, the American Cancer Society or any other organization recommending screening for liver cancer in asymptomatic individuals?

MR. MIGLIACCIO: Same objection.

THE WITNESS: Out of fairness for this question, I really think that we have discussed this at some length just a few minutes ago with my even providing you an example of a subset of higher risk patients with liver disease who would garner such screenings from professional guidelines, but I've even tried to recall for you. And all of this is as a general primary care physician, not an oncologist, not a specialist; and furthermore, not as an expert who was retained to opine on such matters in this case. They're quite far afield from the common methodology of pricing medical services.

BY MR. TRISCHLER:

Q. Do you agree that the medical community leaves the decision to screen for a given cancer type and when to the treating physician based on his or her knowledge of the individual patient and in consultation with that patient?

MR. MIGLIACCIO: Same objection. Vague and incomplete hypothetical.

THE WITNESS: Can you be more specific at all?

BY MR. TRISCHLER:

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Q. No.
A. Okay. Could you provide me any aspects of that clinician's specialty, any aspects of the patient's preference, any aspects of shared decision making, and any aspects of what guidelines you're referring to in that question?
Q. No. I didn't refer to guidelines, so you just do what you want to do. There's no reference to guidelines in that question, sir.
A. You asked me about decisions. I've already established before that decisions are informed by guidelines.
Q. Are you going to answer my question or not?
A. I am.
MR. MIGLIACCIO: Objection.
THE WITNESS: I'm on my way to --
MR. TISCHLER: Then answer it, please.
THE WITNESS: Okay. Guidelines do differ in some ways, so if you're going to ask me about how clinical decisions are made between physicians and patients, I think it is only fair that you provide some context about the role of that physician. Is it a generalist? Is it a specialist? The guidelines that you are thinking of that would

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inform such a decision, because guidelines do differ a bit; and importantly, the patient's preference for that screening modality. And a purely hypothetical question that's devoid of such important detail is very difficult and, in my view, clinically inappropriate to answer.

BY MR. TRISCHLER:
Q. All those factors that you just outlined need to be considered on a case-by-case basis. Right?
A. I disagree with your characterization of a case-by-case basis and this is the clinical nuance that, to be totally honest with you, sir --
Q. Please, just answer.
MR. MIGLIACCIO: Objection to the harassing colloquy. Let him answer his question.
THE WITNESS: It's okay. I don't mind, sir. And despite your chuckle, I do really seriously mean that in day-to-day clinical life, we must balance the generality and the universality in the uniformity of screening guidelines, which are applied to subpopulations, large subpopulations of the entire U.S. population with patient preferences, physician beliefs, physician specialty and shared decision

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making in that discussion. And it is not, therefore, correct, your characterization, because screening guidelines offered by professional societies, which we've talked about at some length today, they recognize that despite some individualized differences between patients, such general guidelines about screening for cancer are still well-founded on rigorous avenues, still recommended for subpopulations of the entire nation's population and still ought to be done by and large or on average by physicians. And that clinical nuance, if you want to focus on my expert as a clinician, which is outside of the scope of my work for this report, is essential because, on the one hand, you are trying to establish the differences across patients, but I'm reflecting for you the important fact that despite differences between patients, as a nation and as a medical profession, we have lots of cancer screening guidelines that pay attention to and respect those differences but, nevertheless, recommend universality, uniformity and a coherent set of screening guidelines that supersede those differences. Meaning, they are a common methodology for physicians to consider in terms of cancer screening. And if you're able to work that nuance

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with me, work with that nuance with me, I think our questions and answers can be more clinically precise. If you want to dispose of that nuance, it becomes harder for me to give you clinically precise answers; and that's all I'm trying to inform you of here. I apologize for the long response.

BY MR. TRISCHLER:
Q. Well, that's fine. It's to be expected and it's, actually, a little bit comical because I've been trying to ask you what the guidelines are that need to be followed for these various cancer types, and you haven't -- any of them for bladder, pancreatic, stomach, anything, yet now you go on this long winded answer about saying how we must be mindful of guidelines when we talk about patient screening. I'm trying to find out which ones they are. So tell me.
MR. MIGLIACCIO: We're objecting to that harassing comment.

BY MR. TRISCHLER:
Q. What guidelines exist for -- what published guidelines exist for screening of stomach cancer, name one?

MR. MIGLIACCIO: Objection. He's here to opine on issues relating to the pricing of medical services. If you're asking him other questions, as you have been for hours now, it's outside the scope of his report. You can keep asking, but you're going to get the same answer.

THE WITNESS: Maybe I can try to level -- would you like to talk about colorectal screening, sir?

BY MR. TRISCHLER:

Q. No, I didn't ask about that. I'd like an answers to my questions. That's the way this works. So my question is: Can you cite any NCCN or USPSTF published guidelines on stomach cancer screening?

A. And again, my first clarification needs to be, for whom are you considering? For what patient population are you asking?

Q. For any patient population.

MR. MIGLIACCIO: Same objection. Beyond the scope.

THE WITNESS: Right. And the conceptual basis of many of my previous answers for you was that screening for high risk individuals is different than

screening for the general population. In this case we're talking about, this matter pertains to individuals having been exposed to carcinogens, which by definition makes them a high risk subpopulation. I'm asking you to be specific about the population of patients that you're asking me about and you're emphasizing the asymptomatic overall U.S. population, I think. Therefore, my answers for you minutes ago, my answer for you now is, as a primary care physician and not an oncologist, I cannot cite for you or recall a guideline for stomach cancer, screening for the asymptomatic overall U.S. population in the absence of any subpopulation characteristics that you're able to provide.

BY MR. TRISCHLER:

Q. Do you read the AMA Journal of Ethics?

A. Ethical training is an essential part of our medical school curriculum and my training as a physician. I have read the American Medical Association's Code of Medical Ethics. You said journal, I believe the right word is code of medical ethics, before. I would be happy to answer any follow-up questions about medical ethics.

Q. Before you do that, can you answer the

question that I asked? Do you read the AMA Journal of Ethics, yes or no?

A. I've read the AMA Code of Medical Ethics.

Q. All right. Do you read the Journal of Ethics?

A. If there is a specific journal title called the American Medical Association Journal of Medical Ethics, it's quite possible that I read that in my life as a researcher and my student -- my life as a student training to be a research or an independent investigator researcher. I can't recall for you exactly in my ten plus years of training and doing research when I would have read that, but I can be more affirmative and definitive for you that I read the AMA Code of Medical Ethics, which I think, plausibly, should be consistent with what the AMA Journal of Ethics, as you purport, would recommend for physicians in the U.S.

Q. Have you -- the AMA Journal of Ethics published a commentary in which the author wrote that: "Just because a procedure can be done, doesn't mean it should be done."

Do you agree with that statement?

MR. MIGLIACCIO: Objection. Vague.

Incomplete hypothetical. Outside the scope.

THE WITNESS: That is a highly hypothetical characterization of all medical decisions for all patients and you would need to provide me with some specificity for me to answer that question. And I would actually give you -- I would lend you a further olive branch here, so to speak. I've done research, original research, some of which is cited in Attachment B, that address the appropriateness of clinical services. But as you'll see in all of my peer reviewed papers and that of my colleagues in the field studying the appropriateness and quality of care, the critical study of a subject like that requires you to be specific about what service, for whom, what physician and what circumstance. And if you were to ask me a generality like that, it's not appropriate for me to provide a vague answer. So if you will, please, any specifics would be very helpful.

BY MR. TRISCHLER:

Q. If you can't answer the question because it's too difficult for you, just say so, sir.

Do you agree with the principle that "just because a procedure can be done, doesn't mean

it should be done?" Yes or no or you can't agree, you need more information, just give me an answer. It's not a hard.

MR. MIGLIACCIO: Objection. Asked and answered. He provided you his answer and you just ignored it.

THE WITNESS: Yeah. In an effort to be brief here, in addition to the fact that this is well outside the scope of my work in this case, if you look at my work on the quality of care and the appropriateness of care, appropriateness is an important clinical consideration for physicians, for researchers, for the policy making community, and for the patient community. Inherent in your question is, do we think about appropriateness of care? Yes, we think about the appropriateness of care. Are all medical services completely appropriate in all cases for all patients? Certainly not. That does answer your question, sir. But the reason that your question does not merit an overall general "yes" or "no" is that it lacks any clinical detail for any expert, clinical or economic or otherwise, to assess the specific service, the patients, and the providers in the clinical situations in which it's rendered. And those are, you know, factors that, if you read

the papers I've written on quality and appropriateness, are important for such assessments.

BY MR. TRISCHLER:

Q. Do you agree that treatment guidelines may be followed in some instances and may be disregarded in others?

MR. MIGLIACCIO: Objection. Vague. Incomplete hypothetical. Outside the scope.

THE WITNESS: I could not speak for all physicians, obviously. In addition to the fact that this is, again, outside the scope of my work in this case and what I was retained to opine on, as a general research matter in health services research and health policy research, there is evidence showing that physicians do vary in what they do. There is variation between physicians in the care that they provide. That's an empirical fact from the research literature. That's probably the best way I can answer your questions with facts, with that empirical fact.

BY MR. TRISCHLER:

Q. Do you agree that decisions regarding patient care must be individualized based on

knowledge of both the individual patient and the available medical evidence on risks and benefits?

MR. MIGLIACCIO: Objection. Vague. Incomplete hypothetical. Outside the scope.

THE WITNESS: I would ask for you to please be more specific, but I can start an answer by saying that it depends on the clinical situation. In some cases, guidelines supersede individual differences across patients, especially in situations where patients may be very high risk for a bad outcome and in other cases where patients may be at very low risk. Or in other clinical scenarios, it could be more plausible that patient preferences and other factors carry greater influence over the clinical decision. So it depends on the clinical situation, which you have not provided me any details for. So if you could please do that to some extent, I could give you a more precise answer to the situation.

BY MR. TRISCHLER:

Q. Let me go back to the nine cancer types that are at issue in this litigation.

A. Okay.

Q. Are there some proposed class members to

be excluded from the screening for one or more of these nine cancers? Or are you suggesting that screening should be done for all nine cancer types for all class members?

MR. MIGLIACCIO: Objection. Vague. Misstates.

THE WITNESS: I do not have a formal opinion to render on that issue for you in this case, sir, because that is well outside the scope of what I was retained to opine on.

BY MR. TRISCHLER:

Q. Well, you do offer a framework for screening in your report?

A. I offer illustrative examples of a set of services that could comprise the start or the foundation of potential medical monitoring program. But those examples are meant to be illustrative rather than as a recommendation or as a framework for the final screening program, which again, has not yet been determined or certified.

Q. Are there any risks to the screening procedures that you propose as part of your framework that is yet to be finalized?

MR. MIGLIACCIO: Objection. Misstates.

Outside of the scope.

THE WITNESS: Which services are you referring to?

BY MR. TRISCHLER:

Q. The ones in your report.

A. Would you mind being more specific? We have the report in front of us. Would you mind pointing to which services you would like me to answer about?

Q. The ones that you mentioned as illustrative and a framework for this yet-to-be-finalized monitoring program. You cited them in your report. Do you need me to remind you what they are?

A. No, I only am asking for you to be more specific and if you would like to not be more specific, then I'm happy to go through the six illustrative examples I've provided one-by-one and answer your question in turn for each. Would you like me to do that for you?

Q. I'd be delighted.

A. Okay, let me pull up my report. I'm on Page 24 of my report, which contains Table 6 and the title of which is "2021 Medicare Prices and Estimated

Medicaid and Commercial Prices". These are six illustrative examples that I provide as the beginning for the potential foundation of a potential medical monitoring program.

So to answer your question, urinalysis, CPT Code 81001, that is a very common service delivered in the U.S. healthcare system. The risks of a patient providing a urine sample are minimal if not none. Patients are asked to do this in the privacy of a private space in the clinic or in a hospital and it is a non-invasive procedure. And, you know, there are guidelines about when urinalyses are appropriate, when they should be ordered and in the fine print of those guidelines, you may well find a discussion of what, if any, risks there are. But as a general primary care physician who has ordered urinalyses for many patients over the years, the risks are minimal to none.

Next, for the complete blood count, 85025, this is a very common laboratory service rendered both on the inpatient and outpatient side. The risks to obtaining a blood sample for not just this complete blood count but for electrolytes, for cholesterol, for blood sugar or any other number of laboratory tests that the U.S. healthcare system

does, the risks are a blood draw. And, you know, on average, population-wide, the risks of a blood draw are also minimal and they are done with such frequency in the U.S.. And, in fact, I have academic papers that I cited in Attachment B that cite evidence that laboratory tests are the most -- as a category -- frequently ordered medical services in the entire country. And despite that frequency, you rarely hear evidence suggesting, or if ever, evidence suggesting that there are prohibitive risks to patients receiving blood draws.

Next, is an office visit. That, I think, is a general matter, perhaps with all of us here on the call perhaps having been patients in our own lives or having had family members or friends as patients, involves walking into a physician's office. What are the risks of walking into a physician's office and sitting down for a physician visit? Well, I would say that the bodily harm of doing that is little to none. Certainly, on average, certainly population-wide, that is also one of the most commonly billed services in the United States, a level four office visit.

Next, for a low dose chest CT Scan, this is part of the screening guidelines for lung cancer

and it is, just to be very precise here, recommended by the USPSTF, the American Cancer Society. The reason that it's low dose, which is specifically stated here, is that these professional societies have determined that that is the way to minimize the risks of screening for lung cancer population-wide for high risk individuals. And again, high risk individuals have a definition and this illustrates why I was, you know, asking you to provide more specificity for earlier questions because it demonstrates that, like in this case, high risk individuals are those 50 to 80 years old now with at least 20 back years of smoking, having quit in the last 15 years, totalling roughly 14 and a half/15 million people in the country; that's a high risk subpopulation of our national population. For those people to further minimize their risk of radiation from CT scans, these professional society guidelines have recommended low dose radiation CT scans. Other than that, the risks of walking into a facility, getting on to a scanner, having the scan taken are minimal to none, in general, in my experience as the general primary care physician.

For upper endoscopy and screening coloscopies, those are performed by our

gastroenterologist specialist colleagues. Those are certainly, to some degree, more invasive procedures than the four examples we just walked through. Upper endoscopies, as mentioned earlier, can be a screening tool used to detect or screen for esophageal cancer, for patients at high risk for esophageal cancer. And, therefore, I was, again, urging you or asking you to provide some specificity with regard to what high risk characteristics you were thinking about in answering your earlier questions because that matters for my clinically nuanced answer. But under -- as far as my knowledge as a general primary care physician and, again, outside the scope of pricing of medical services, I'm not aware of widespread clinical evidence that suggests, on average, substantial harm to patients from upper endoscopies. They're done in a facility setting most often. They're done under a careful conscious sedation or a general anesthesia. They're done with a team of providers. There is counseling beforehand about what the procedure involves. Patients have a chance to answer questions, they consent to the procedure. The procedure is guided by video technology, there are technicians in the room to help make sure that the procedure is safe. So as a general matter, the risks

of that are also minimal.

And lastly, for screening colonoscopies, which, you know, again, are for a specific subpopulation of the overall U.S. population, are the lower GI analogous service to the upper GI endoscopy that we just talked about. And screening colonoscopies, similarly, require conscious sedation or general anesthesia. They're similarly, to some degree, invasive like an upper endoscopy and do require a team of physicians with care providing this in a facility setting, most often; though it can be done in an office setting where there needs to be expertise and care on the part of the gastroenterologist, the endoscopist doing the procedure. But as far as the evidence shows, certainly a part of guidelines, despite any individualized risks of a screening colonoscopy procedure for any given patient across U.S. populations, now starting at age 45, it's recommended that for average risk people even, even for average risk individuals, screening colonoscopies should begin at age 45, population-wide, common methodology, across all people, despite individual differences. That's what the society guidelines say, multiple society guidelines; ACS, USPSTF, and that's another

example of how they've assessed the risks of this procedure. Despite the risks inevitably being a little bit higher or a little bit lower for a given patient, the recommendations say for a large section of the U.S. population having arrived at a certain age, it's recommended for everybody. It's uniform. It's consistent. Okay, I'm going to stop there.

Q. So the six -- so the six components might be a framework for a monitoring plan that you mentioned and you called them illustrative in your report. If I could dare try to summarize the testimony that you just gave me: The suggestion was there may certainly be some risks, but they are minimal and the benefits of the services for the vast, vast majority of the patients would outweigh the risks. Is that your testimony?

A. For the patient populations that I specified.

MR. MIGLIACCIO: You froze, Dr. Song.

MR. TRISCHLER: Yeah, I don't hear anything.

MR. MIGLIACCIO: Yeah, I think he remains frozen.

THE VIDEOGRAPHER: Do you want to go off the record?

MR. MIGLIACCIO: Sure. Is it the time that you need for your break, by the way, Clem?

THE VIDEOGRAPHER: The time is 11:57. This ends media unit No. 2. We're going off the record.

(Luncheon recess: 11:57 a.m.)

THE VIDEOGRAPHER: The time is 1:01. This begins media unit No. 3. We're back on the record.

BY MR. TRISCHLER:

Q. Okay, Doctor, I don't want to plow old ground, but right before our lunch break, I was asking you a question that I think you were in the process of answering when we had some Internet connectivity issues. Basically, to try and get through this as quickly as possible, I had asked you whether there were any recognized risks associated with the procedures that you described in your report as frameworks for a monitoring plan. Do you recall that?

A. Yes, the beginnings or the foundations of a potential medical monitoring program.

Q. And you proceeded to go through those six procedures that are in your report and discuss

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what you perceived as risks. And what the question that I had asked you was, you know, your testimony will speak for itself, but the gist of what I heard was that there are some risks associated with almost all medical procedures. But in your judgment and estimation, the risks of these procedures were minimal for the large -- for the -- most of the patient population. Is that a fair summary of what we had discussed?

A. Perhaps another way of putting it would be, on average, across the patients in which the -- those example services have been rendered or delivered to, the risks are rather minimal to sometimes essentially none.

Q. But, certainly, the risks would not be the same for all patients across the board. Correct?

A. Well, it depends on which patients you're speaking about. Your question was around a general overall population of patients. But for high risk population of patients, such as patients at high risk of developing cancer, for example, then the balance between benefits and risks might be different. So, you know, guidelines, these large national professional society guidelines do not say that there are none or exactly the same risks for

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every single patient. But despite any risks, and as minimal as they are, the benefits of such screening are thought to be greater than the risks and certainly greater enough for them to be recommended as broadly national screening guidelines.

Q. Well, let me see if I can be more specific what I was -- when you talk about colonoscopies, for instance, those are done under anesthetic. Correct?

A. Again, I just want to preface by saying you're asking me about the clinical portion of my life, of my professional life, and that is not what I was retained to opine on in this case. So we are stepping far afield from the substance of my report to you and what I was retained by counsel to opine on. And I'm trying to be as helpful as I can to you but, you know, the first thing I would just emphasize again is on matters regarding oncology, on matters regarding cancer screening guidelines, treating patients with cancer, I defer to experts who are trained in oncology and who are, you know, to my knowledge, part of this case as expert witness who can provide more of that subspecialized expertise. But, you know, if you wanted to ask general questions about colonoscopies that I can perhaps answer as a

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general primary care physician as a clinical matter in my own clinical experience, I'll be happy to do my best.

Q. Well, after that filibuster, that's exactly what I did, Doctor. I said, are colonoscopies conducted under anesthesia?

A. In my clinical experience for my patients, they can be, but not always.

Q. And does anesthesia pose risks for some patients?

MR. MIGLIACCIO: Objection. Vague.

THE WITNESS: My clinical expertise does not span into the risks of anesthesia, the risks of anesthesia for patients. I'm certainly not an anesthesiologist nor am I an endoscopist, so I do not have a formal clinical opinion for you on that.

BY MR. TRISCHLER:

Q. Would you recommend a colonoscopy to an asymptomatic patient who had -- who was diagnosed with congestive heart failure?

MR. MIGLIACCIO: Objection. Incomplete hypothetical.

THE WITNESS: For that hypothetical patient for whom you have not specified an age or

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family history but only a comorbidity of, hypothetically, congestive heart failure for which you've also not said whether it's heart failure of a certain stage or severity, I do not have enough clinical information to be able to give you a precise clinical recommendation for whether that person should be offered a colonoscopy. I think this was answered with some of our previous questions and answers too, where I think more clinical specificity from you would be a better guide for me to give you a more precise answer.

BY MR. TRISCHLER:

Q. Would you agree that there are some patients for whom a colonoscopy might not be recommended?

MR. MIGLIACCIO: Objection.

THE WITNESS: What types of patients do you have in mind?

BY MR. TRISCHLER:

Q. Any patients or should every American on the planet over the age of 45 receive a colonoscopy, regardless of their medical history, comorbidities or any other underlying medical condition?

MR. MIGLIACCIO: Objection. Outside the scope.

THE WITNESS: As far as I understand your question, you're asking me now about what the guidelines state.

MR. TRISCHLER: No, I didn't.

THE WITNESS: That's how I'm interpreting your question.

MR. TRISCHLER: Well, then you're wrong.

BY MR. TRISCHLER:

Q. I'm asking you -- I'm not asking you how you interpret the guidelines. I'm asking you for your opinion as to whether every -- whether it's your belief that every American over the age of 45 should undergo a colonoscopy, regardless of their medical history and regardless of any underlying comorbidities.

MR. MIGLIACCIO: Objection. Outside the scope.

THE WITNESS: I'll provide you an answer in two parts. The first part is that I defer to screening guidelines for a question like that. Your question is essentially about one's clinical opinion, which in this case is informed by our national

guidelines. And second, I can give you one concrete example where the answer to your question would be no, not for everybody over the age of 45. And that's because, as a general primary care physician, I have had clinical experience interpreting guidelines for colorectal cancer screening. And the guidelines, depending on which society you referred to, generally say that beyond the age of 85, universal screening for colorectal screening is no longer systematically recommended. So that's a concrete example of no, not everybody above the age of 45. It's also a demonstration of how further clinical detail or nuances is helpful for a question like this.

BY MR. TRISCHLER:

Q. Are there other examples of individuals over the age of 45 who you would not recommend receive a colonoscopy?

A. As a primary care physician sitting here and not an oncologist and not having been asked to opine on matters such as this regarding guidelines, I do not have a formal opinion for you on that and this, again, falls well outside of the scope of what I was asked to opine on in this report.

Q. We've been talking a lot about

guidelines, one of which is the USPSTF. Right?

A. Yes, USPSTF.

Q. And that stands for U.S. Preventive Service Task Force?

A. Preventive Services Task Force, yes.

Q. All right. Do you agree that those guidelines are subject to the treating physician's clinical discretion?

MR. MIGLIACCIO: Objection. Incomplete hypothetical, outside the scope.

THE WITNESS: That's a very hypothetical question about how every physician uses guidelines as a matter of, and also outside, again, the scope of my work for this case. I have not assessed that question systematically for physicians out there nor researched the evidence space about how physicians respond to those guidelines.

As a general primary care physician, again, I'm trying to be helpful here to you. As a general primary care physician, I have certainly made every good faith effort to follow the guidelines and respect my personal discussions with my patients in arriving at my clinical decisions with my patients.

BY MR. TRISCHLER:

Q. For your own clinical practice, sir, do you feel that you're bound to follow the USPSTF guidelines? Or can you vary from them when your clinical judgment dictates that that is the appropriate course of action?

MR. MIGLIACCIO: Objection. Outside the scope. Are you ever going to ask him about how he calculates the price associated with the service? That's what he's here to opine about.

THE WITNESS: It depends on the patient and the clinical -- the clinical situation at hand. It is -- it is certainly true that, despite individual differences across patients, guidelines can and often do direct physicians to provide on average appropriate preventive care superseding recognized individualized differences across patients. We've talked about this before this morning. I don't know that it's appropriate for me to give you a personal patient anecdote or offer expertise on this kind of specific clinical decision in a given situation without further detail from you, you know, and without seeing the connection to the pricing of healthcare services. So it depends.

BY MR. TRISCHLER:

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Q. So are you refusing to answer the question?
A. I don't think I've refused, sir, I'm just trying to explain --
Q. Okay. Well, then, do you view the -- do you view the USPSTF guidelines as mandatory or do you have discretion to deviate from them when your clinical judgment suggests that that's the right course of action for a patient?
MR. MIGLIACCIO: Objection. Asked and answered. Outside the scope.
MR. TRISCHLER: Outside the scope is not a proper objection, Nick. You've made it about 40 times in violation of the discovery orders of this court. I wish you'd stop.
MR. MIGLIACCIO: I wish you'd ask him questions about his report, but you don't seem to be doing that either.
THE WITNESS: If I heard you correctly, sir, did you phrase your question as do I find the USPSTF guidelines to be mandatory?

BY MR. TRISCHLER:
Q. Would you like the question read back? Would that help you answer the question directly? If

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it would, I'd be happy to have the court reporter do that.
A. No, it's okay. Let me just make my best of effort here. As far as I understood your question, you asked whether I find USPSTF guidelines to be mandatory. Well, by the very nature of guidelines, they are recommendations. I don't equate recommendations with mandatory orders.
Q. Have you ever served on a USPSTF expert panel?
A. No, I have not.
Q. Have you ever been affiliated with the National Cancer Institute?
A. No, I have not.
Q. Have you ever developed any screening recommendations for any cancer type that were published by USPSTF or the National Cancer Institute?
A. As we discussed earlier this morning, no, I have not.
Q. Have you ever published any peer reviewed papers recommending a screening program for any cancer type or proposing guidelines on any cancer screening?
A. Recommending or proposing any screening guidelines, not in that way. In some of my research

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papers, you will find, likely in the introductory section or the discussion section, general statements about high value care, clinically appropriate care that are -- consistent with what guidelines recommend -- (Internet froze.)
Let me just try again. My answer was not exactly in those words because in my published academic papers you will find, likely in the introductory section or the discussion section, statements about delivering high value care, clinically appropriate care as a health policy and research matter that is, in spirit, consistent with what the guidelines recommend. But outside of that, in my academic work, no, in the way you phrased your question.
Q. What value is a low dose CT Scan of the chest in evaluating the liver cancer?
MR. MIGLIACCIO: Objection. Vague. Incomplete hypothetical.
THE WITNESS: I was not asked to opine on such questions as that. I have not looked into that question. I do not have a formal opinion on that question for you.

BY MR. TRISCHLER:

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Q. Well, a low dose CT Scan is one of the foundations of a medical monitoring program that you cite in your report; is it not?
MR. MIGLIACCIO: Objection. Misstatements testimony. You can answer.
MR. TRISCHLER: Thank you.
THE WITNESS: Yes, but you asked about the use of that low dose chest CT Scan for liver cancer, not for lung cancer.

BY MR. TRISCHLER:
Q. I know. Liver cancer is one of the nine cancers that the plaintiffs claim to be at issue here. So I'm asking about how is one of these foundational elements of your monitoring program of any value in evaluating for liver cancer?
MR. MIGLIACCIO: Objection. Misstates testimony.
THE WITNESS: In the context of my report and even in our discussion of low dose CT cancer screening earlier this morning, the use of low dose CT cancer screening as an example for illustration purposes in my report, pertains to screening for lung cancer not liver cancer. You've asked me a question about applying that screening

test for liver cancer and my honest response to you is, I have not looked into that clinical question and I was not retained to do so, I did not do so in writing my report and sitting here with you at the moment, I have not done that investigative work, so I don't have an opinion on that application of the test for you.

BY MR. TRISCHLER:

Q. Is upper endoscopy of any clinical value in screening for bladder cancer?

MR. MIGLIACCIO: Same objection.

THE WITNESS: An upper endoscopy is used in some cases to -- in certain situations, pardon me, to screen for esophageal cancer. Any relationship that an upper endoscopy has with other cancer types is not something that was germane to my clinical training, it's not something that I have prior knowledge about, and is not something I have had a chance to look into nor is it within the scope of my work for this case to date.

BY MR. TRISCHLER:

Q. Have you ever published any papers dealing with the toxicological effects of NDMA or

NDEA exposure?

A. No, I have not.

Q. And before you were retained in this case, I think you told me that you've never independently researched the carcinogenicity of NDMA or NDEA. Correct?

A. Because that was not within the scope of what I was retained to opine on; to date, correct, I have not looked into that question.

Q. My question was: Before you were ever retained in this case, you had never done any independent research in the carcinogenicity of NDMA or NDEA. Right?

A. Ah, I see. Thank you for that clarification. Prior to being retained for this case, to my knowledge and my recollection, I have not done original investigation into that question.

Q. And NDMA and NDEA fall within a class of compounds known as nitrosamines. Are you aware of that?

A. To the extent of my knowledge, especially that most recent knowledge supplied by the documents in this case, that is my general understanding. Although, I would need to defer to colleagues in oncology and other subspecialists, such

as toxicologist or an oncologist for a question such as that.

Q. And do you understand that nitrosamines are ubiquitous?

MR. MIGLIACCIO: Objection. Assumes facts not in evidence.

THE WITNESS: I was not asked to think about or opine on nitrosamines. So a question about nitrosamines with respect to its ubiquitousness is not something that I have a formal opinion on at this time.

BY MR. TRISCHLER:

Q. Each and every one of us are exposed to nitrosamines, including NDMA or NDEA, on a regular basis; are we not?

A. I was not retained to opine on that question. I have not looked into that question. I don't have an opinion on that question at this time.

Q. Well, I appreciate that. I wasn't really asking you as an opinion. Do you know as a matter of fact whether each and every one of us are exposed to nitrosamines, including NDMA and NDEA, on a regular basis?

A. I'm referring back to all of my training

as a general primary care physician and I cannot recall a time when I received specific clinical training on that issue, so I don't have an opinion on that. I don't have an answer for you on that question.

Q. So since you've become involved in this case, are you aware of research suggesting that nitrosamines, including NDMA or NDEA, can be found in the food we eat, the water we drink and the air we breathe?

A. Again, I was not asked to look into that question and I have not taken the time to examine such literature as you've connoted here in that question.

Q. Well, you've read a lot of stuff about the issue, the issues in this case that you weren't asked to opine on.

A. I'm sorry, what was your question?

Q. I said, you've read a lot of materials that include discussion of issues that you were not asked to opine on, like, you told us about Dr. Panigrahy's report, Dr. Hecht's report. They cover lots of issues that you weren't asked to opine about, but you read them anyway. Right?

A. I certainly did read them back in

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September, October -- or rather October and November time period. I don't recall off the top of my head here today specifics regarding the ubiquitousness of nitrosamines. And I would offer, if they have provided you evidence or citations or formal opinions with regard to that, I defer to them as experts in the field. Just as, by the way, for so many of the questions you've asked me, I emphasize that I am a primary care physician, not an oncologist, not a toxicologist. As routine in our medical practice, we rely on the expertise and opinion of our specialty colleagues in making clinical decisions. And this is analogous here. Seems like if there are specialty colleagues here or other specialty experts with the particular training in such questions, my analogous role would also be to defer to them, even if I've read their reports months ago. You know, I think it's reasonable that deferring to that more subspecialty expertise is appropriate for me as a primary care physician.

Q. All right. Well, thanks for that nonresponsive commentary. But let me see if I can get an answer to the question because the only question I asked you was: Have you read, you, Dr. Song, have you read anything since you've been

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involved in this case suggesting that NDMA and NDEA can be found in the food we eat, the water we drink and the air we breathe?

MR. MIGLIACCIO: Objection. Asked and answered. Object to the colloquy there.

THE WITNESS: What I recall, at the moment, regarding nitrosamines in the material that I've read in the context of this case is that they were contaminants in Valsartan-containing drugs, that many individuals were exposed to them through the drugs. And that really is the extent of my recollection about their ubiquitousness and I would need to reconsult those reports to give you an answer about other aspects of nitrosamines.

Q. In your clinical practice, have you ever diagnosed a patient with cancer due to NDMA or NDEA exposure?

A. Can you be more precise about diagnosis? What do you mean by diagnosis there?

Q. What's the medical definition of diagnosis or diagnose?

A. Well, I don't mean to put my teaching hat on here, but cancer diagnoses are made in almost all cases of solid tumors based on tissue diagnoses and pathologists' reads. So we've already

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established earlier that I'm not a pathologist; therefore, I never read a pathology slide of a tissue biopsy and formally made the diagnosis of cancer as a pathologist. And liquid malignancies also require a diagnostics step with a specialist, whether that's an oncologist or other specialist. So, because that is the clinical working definition of a diagnosis, which is why I want to be precise about that, I, in my role as a primary care physician, am not in a position to formally diagnose the existence of a cancer.

Q. Have you ever attributed a patient's cancer in your clinical practice to NDMA or NDEA exposure?

A. Such attribution would, in almost all cases, come from specialists, such as an oncologist or perhaps a pathologist or perhaps a toxicologist. Given that my specialty is not in those domains, I would also not be in an appropriate position to attribute causation in cancer for my own patients in a formal clinical sense.

Q. Are you aware of any generally accepted test method that exists to enable one to attribute a given cancer type in a particular patient to NDMA or NDEA exposure, as opposed to any other risk factor?

MR. MIGLIACCIO: Objection. Vague.

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Incomplete hypothetical. Outside the scope.

THE WITNESS: I recognize the vagueness of that question; and frankly, it falls outside of my clinical expertise and as well outside the domain of my expert opinion for this case.

BY MR. TRISCHLER:

Q. All right. Does that mean you don't -- (audio dropped) that would enable a clinician to attribute a given cancer type to NDMA or NDEA exposure?

MR. MIGLIACCIO: Same objection.

THE WITNESS: I also think you broke up a bit there. I don't think I caught your second or third word, but with the rest of what you said, which I think I understand, that exceeds my clinical training, sir. So I'm here as a health economist. I'm also here, you know, outside of the scope of what I was retained to do as a practicing clinician. In my clinical training in both of these professions, I have not received enough training to be able to answer that question.

BY MR. TRISCHLER:

Q. You've talked several times today about

high risk patients. Do you remember using that term?
A. Yes, I remember using that term earlier today.
Q. Does NCCN define high risk patients?
A. I don't recall off the top of my head whether those guidelines specifically use the word "high risk". They may use additional, more specific words to connote or denote high risk. In my professional life as a general primary care physician and in my answers to you earlier, high risk is meant to capture people who are at a higher probability of developing a bad outcome, such as a cancer.
Q. Yeah. I appreciate that. I'm sorry I didn't mean to cut you off. I appreciate that. I wasn't looking for your definition. Does NCCN define the term "high risk"?
A. I don't recall the exact words they use.
Q. Does USPSTF define the term "high risk"?
A. Their guidelines certainly, to the extent of my knowledge as a primary care physician, describe higher risk subpopulations of a more general population. I can give you a very concrete example to illustrate that point. Let's take one of the things that we've talked about earlier, such as colonoscopies. The USPSTF clearly states that higher

risk individuals should receive a more intensive regimen of screening, either more frequent or starting at an earlier age. And in that, as you can tell, is a reflection of the higher risk that that subpopulation of individuals have or has.
Q. In your clinical practice since 2017, do you treat patients who took recalled Valsartan?
A. As best as I can recall, and I'm going through my inpatient clinical experience in recent years and my outpatient primary care panel, which is why I'm taking a second to think through my patients, I cannot recall a specific example of a patient, either on the inpatient wards or on the outpatient primary care clinic setting, who has consumed contaminated Valsartan. But to the extent that those patients exist in my panel or in the inpatient setting, it's possible that they may have not been brought to my attention yet.
Q. Are you aware of scientific research establishing that all humans form nitrosamines indigenously?
A. That is beyond the scope of what I was asked to do. I have not had a chance to look into that question and, sitting here at the moment, it is outside of the training that I received to date.

Q. Assume that every person in America is exposed to nitrosamines, including NDMA and NDEA, on a regular basis and that all of us indigenously produce nitrosamines. Should cancer screens for asymptomatic patients be put in place across the entire American population?
MR. MIGLIACCIO: Objection. Vague. Incomplete hypothetical.
THE WITNESS: That is a perplexing and I might even offer a potentially misleading hypothetical here and it falls well outside the scope of what I've spent my time and effort opining on in this case. I would defer to other experts in this case for a question as general and vague as that.

BY MR. TRISCHLER:
Q. Has the American Medical Association ever recommended or endorsed cancer screening for individuals exposed to NDMA or NDEA?
A. Again, because that's a question outside the scope of what I was retained to do, I've not had a chance to try to answer that question with my own research.
Q. Sitting here today, do you know if the AMA has ever endorsed cancer screening for anyone

exposed to NDMA or NDEA?
A. Off the top of my head now, no, not at the moment.
Q. Has the American Cancer Society ever recommended or endorsed cancer screening for anyone exposed to NDMA or NDEA?
A. Similarly --
MR. MIGLIACCIO: Objection. Vague and incomplete hypothetical. But go ahead.
THE WITNESS: Similarly, I have also not been asked to track down that guideline, if it exists. And therefore, because I have not spent time examining that question, I don't have an answer for you at the moment.

BY MR. TRISCHLER:
Q. Well, as a clinician treating patients every day, do you know whether the American Cancer Society has ever recommended or endorsed cancer screening for individuals exposed to NDMA or NDEA?
MR. MIGLIACCIO: Same objection.
THE WITNESS: Off the top of my head, I cannot recall seeing such a guideline.

BY MR. TRISCHLER:

Q. Has the FDA ever endorsed or recommended cancer screening for anyone exposed to NDMA or NDEA?

MR. MIGLIACCIO: Same objection.

THE WITNESS: And my same response to you, sir. I have not been asked to look into that question. I have not had time to look for that or look into that and sitting here today, I don't have an answer for you at the moment.

BY MR. TRISCHLER:

Q. Well, as a clinician taking care of patients on a daily basis, which you told us that you do, are you aware of whether or not the FDA has ever recommended or endorsed cancer screening for patients exposed to NDEA or NDMA?

A. I don't recall having come across such a guideline.

Q. When you have new patients come into your practice, do they have to fill out, you know, a questionnaire, like you do when you go to most doctors to start new treatment with them?

A. It can depend on the patient. Most patients that I've received as new patients for a new intake visit have some history with Massachusetts General Hospital and have some clinical notes or

prior testing or prior encounters. Therefore, in our first visit, I generally take the time to meet a new patient to talk about the patient's life, family, work, and then review their clinical history as best as I know from their prior records. And typically, through that process, we can construct what would otherwise be done in a more natural, organic and, I would say, beneficial way for the doctor/patient relationship as what a survey could do. But there are also times in my practice, especially in prior years, where a survey has been used, so it varies depending on the situation.

Q. And in your -- in your clinical practice, I think you said you see patients at, I think you called it the clinic at Mass General. I don't want to mischaracterize it, but is that what it's called?

A. Oh, no problem. Thanks for clarifying. Yes, so we have one -- the clinic I practice in is one of several main primary care clinics on the campus of Massachusetts General Hospital. It's not the only one. It's one of the largest adult medicine primary care practices within Mass General.

Q. Okay. So if I show up at the clinic for the first time, what you said is that sometimes

there's a written survey that I have to answer and sometimes there's not. Right?

A. Yeah, and I imagine my colleagues in clinic have different preferences about whether they would administer a survey or simply meet the patient and speak with the patient more organically. I've done it both ways as a trainee and as a practitioner after training.

Q. On the survey form used at Mass General, when you're developing, you know, treatment plans and putting in place treatment modalities for new patients, is there a -- do you ask patients on the questionnaire whether they've been exposed to NDMA or NDEA?

A. To the best of my clinical recollection, the surveys, which again were in years prior as I noted before, tended to focus on prior medical history, family history and current symptoms. And I don't recall a specific instance where there was a specific question asks, as you've asked about here, pertaining precisely to particular carcinogens like NDMA or NDEA.

Q. Do you agree with me that no public health agency in the world and no respected medical society has advocated for broad screening of

asymptomatic individuals based solely on exposure to NDMA or NDEA?

MR. MIGLIACCIO: Objection. Vague. Incomplete hypothetical.

THE WITNESS: I appreciate the question, but I think you would also agree my clinical expertise is limited to, my clinical exposure is limited to guidelines that have been a part of my practice from the United States. I'm a physician practicing in the United States after all. So when you ask me about any professional societies around the world, I'm not privy to nor are we trained to practice based on guidelines outside of the United States.

MR. TRISCHLER: Fair enough. I'll rephrase the question.

BY MR. TRISCHLER:

Q. Are you aware of any public health agency in the United States or any respected medical society in the United States that has advocated for broad screening of asymptomatic individuals based solely on exposure to NDMA or NDEA?

MR. MIGLIACCIO: Same objection.

THE WITNESS: To my knowledge, to date,

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I'm not aware of a formalized guideline, such as the colorectal cancer screening or lung cancer screening guidelines that we've talked about in some depth that analogously applies to these carcinogens. That is not to say that such professional guidelines and the individuals that comprise them haven't talked about these carcinogens. That's not something I'm privy to.

BY MR. TRISCHLER:

Q. Either based on your clinical practice or your work in this case, are you aware of any peer reviewed medical literature that has concluded that exposure to NDMA or NDEA necessitates long-term medical monitoring of asymptomatic individuals?

MR. MIGLIACCIO: Same objection.

THE WITNESS: In such a question about my knowledge of the medical literature, because I was not retained to think about this question, I have not had a chance to research the medical literature pertaining to this question. So I don't have an opinion for you not having done that yet to date.

BY MR. TRISCHLER:

Q. Okay. I appreciate that, but I wasn't

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really asking for your opinion. I was asking whether you're aware of any peer reviewed literature that has concluded that exposure to NDMA or NDEA necessitates long-term monitoring or cancer screening of asymptomatic individuals?

A. Okay. Thanks for clarifying. And because I have not looked into the literature pertaining to this question, at the moment, I'm not aware of the type of studies that you just described.

Q. As part of your work in this case, have you reviewed the medical records of any of the medical monitoring class plaintiffs?

A. No, because it is well outside the scope of what I was asked to do for this case.

Q. Do you know who the class plaintiffs are?

A. Not by name off the top of my head because it's unrelated to how medical services are priced in the U.S. healthcare system, which I've also answered several times before.

Q. And I take it you've never talked to any of those plaintiffs?

A. That is correct, I have not.

Q. You have not reviewed any of their deposition testimony?

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A. That is correct, I have not because the pricing of medical services is unrelated to the names or the records of any particular individuals because the pricing of medical services is done in a uniform fashion, in a common fashion that, you know, my report goes into detail describing.

Q. Bear with me a second, please.

A. Sure. No problem.

MR. TRISCHLER: Can we -- I'm going to ask my colleague because he's more adept at documents than I am. Frank, are you able to pull up the EMA Lessons Learnt publication?

(Technical difficulties.)

(Whereupon, a discussion takes place off the record.)

MR. TRISCHLER: Thanks, Frank. So we'll mark this our next sequential exhibit, Dr. Song. I don't know if we're up to No. 6 or.

MR. MIGLIACCIO: Five, I think.

MR. TRISCHLER: Five, okay. Whatever the number is.

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(Whereupon, Exhibit ZS-5 was marked for identification.)

BY MR. TRISCHLER:

Q. And this entire document should be available in the chat, either now or very shortly, but I'll represent to you that what I put in front of you as Exhibit No. 5 is a document from the European Medicines Agency. It's entitled "Lessons Learnt From Presence of N-Nitrosamine Impurities in Sartan Medicines"?

Do you see that, sir?

A. I see the title of that report as you've just read it, yes.

Q. And have you ever heard of the European Medicines Agency?

A. I have not, sir.

Q. I'll represent to you that it's the European equivalent of the FDA for countries in the European continent. Okay?

A. When you say "equivalent", do you have any more information about -- I'm not trying to be difficult here. I just have never heard of this agency and I don't know how they conduct their work or who is on the committees or panels. I really have

no information about them, so I know something about the FDA, but can you be a little more specific about how they do their work?

Q. No, not really. It's a regulatory agency that approves and monitors drug safety in European nations.

A. Who are they comprised of? Do you know the types of experts? Is it basic scientists, clinicians, public health experts, epidemiologists, or other folks from government in these groups?

Q. I don't know. Perhaps the experts from whom you've read their works, like Dr. Panigrahy and Dr. Hecht and all those fine scientists can help you answer that question. But let me ask, let me ask mine.

MR. TRISCHLER: Frank, can you scroll ahead to I think it's Page 9 of the document.

THE WITNESS: By the way, I just want to let you know, the document is not yet in the exhibits folder, so I can't access it at the moment. Let me just try again here.

MR. STOY: Doctor, if you refresh now, it should be in there.

THE WITNESS: Oh, okay. Thank you so much, Frank.

MR. MIGLIACCIO: I'm going to state for the record, it appears to be a 98 page document that we're looking at Page 9 of right now.

THE WITNESS: It's taking a while to load here on my computer.

MR. TRISCHLER: And Frank, the document that I wanted to draw the witness's -- the page that I wanted to draw the witness's attention is not Page 9 of 98. It's actually Page 18 of 98. It's numbered Page 9 of the document.

And you can take the time to read as much of this document as you like, Dr. Song. I want to draw your attention, though, and ask you a question about the paragraph that starts with the question on, "Question of protecting patient's health."

If you could highlight that for me please and sort of blow that up. Could you enlarge that for the witness, please?

BY MR. TRISCHLER:

Q. Okay. And if you read this paragraph, Dr. Song, what EMA wrote was: "On the question of protecting patients health, CHMP did not find evidence to support cancer screening or additional

monitoring of patients exposed to nitrosamines. First, the theoretical risk of cancer was very low and was itself based on a worst case scenario. Second, the screening methods themselves carry risks for the patient. Third, there was considerable uncertainty as to which organs or tissues could be at risk from cancer."

Do you see that language?

A. As you have just read it, that matches the highlighted portion on my screen.

Q. And based on what you just told me a moment ago, you have not done any independent research to call into question the accuracy of the conclusions published by EMA. Correct?

MR. MIGLIACCIO: Objection. Assumes facts not in evidence.

THE WITNESS: As we just talked about a minute ago, I don't have prior knowledge about this European agency. I don't have any knowledge about how they conducted this work, who was a part of it, what evidence they reviewed or anything regarding this report, to be honest. And I am seeing this for the first time and certainly have not had a chance to read it and digest it. I don't feel it's appropriate for me to render any opinion or answer substantive

questions about this report because I'm seeing it for the first time. And in my quick scroll through of pages arriving at this page, there seems to be a pretty dense report that would take some time to process through with basic science and things of the like. So I don't feel that I've had a chance to really think through this report. What you've read here is what's highlighted on the screen.

BY MR. TRISCHLER:

Q. Well, earlier you told me that you were not aware of any public health agency or any medical society that had advocated for broad screening of asymptomatic individuals based solely on their exposure to NDMA or NDEA. Right?

A. Well, because I've not yet had a chance to look into that question and it was not something I was retained to opine on or do in this case. I had not yet gained knowledge enough to answer that question and I don't see how that pertains to this report directly.

Q. Well, since you've not had a chance to look at that question, then you obviously don't have any information to refute or call into question EMA's conclusions that cancer screening for individuals

exposed to nitrosamines is not necessary.
MR. MIGLIACCIO: Same objection.
THE WITNESS: Well, using your logic, sir, if I have not had a chance to review any of this material, how could I formulate any opinion about it in refutation or in support of anything of substance? Again, as I've said just a moment ago, this is the first time that I've seen this document. What would you like me to do with regard to this document that you've uploaded here?

BY MR. TRISCHLER:
Q. So far, just answer my questions. But if there's something you'd like to do, let me know.
A. Well, I don't know that it's practical for me to read through this whole report and process it. It seems long enough that it might take the rest of the day for us. So out of respect for your time and that of others, let me hand the microphone back to you and let you direct where you want me to go here.
Q. Well, the only place I want you to go is with an answer to my question and that is: Can you cite for me any studies that call into question the conclusion from EMA that cancer screening for

patients exposed to nitrosamines is not necessary?
MR. MIGLIACCIO: Objection. Asked and answered. Outside the scope.
THE WITNESS: Again, I've not been retained to work on that question. If asked to do so, I can take the time and effort that that question would deserve to read this material, look into the literature, do my primary independent investigation of that question. But I would just emphasize for you, sir, and I don't mean to be repetitive, that my work in this case pertains to the pricing of medical services within the United States healthcare system and this is well outside the scope of that work.

BY MR. TRISCHLER:
Q. You say it's outside the scope of the work, but if we're going to -- in fairness, if we're going to put in place a monitoring program, we would only want to include within that program services that were necessary. Correct?
A. Well, in fairness, I defer to the fact finder or decision maker in a case like this with regard to what the final monitoring program would include. Remember my framework of prices times quantity equals spending. Part of quantities is

determining who is in the final class that's certified and what services are in the final monitoring program that's certified. Because neither of those certifications have taken place and because I've emphasized my work is on the pricing of medical services, that is outside the scope of what I'm doing and a better expert for answering a question like that would be an oncologist, for example.
Q. So you're going to opine on the costs of a monitoring program, but you're not equipped to describe what the necessary elements of that program are. Agreed?
A. I disagree with your use of "equipped". I have expertise in areas outside of what I was asked to opine on for this case. I have, to date, not applied that expertise to many, if not most, if perhaps not all of the questions you've actually asked during today's meeting. And it's not that I'm not equipped to do any of that work, it's that I have not, to date, been retained to do any of that work or look into any of those questions.
Q. Do you -- strike that.
MR. MIGLIACCIO: Can we take a break for two minutes, please?
MR. TRISCHLER: Sure.

THE VIDEOGRAPHER: The time is 2:01. This ends media unit No. 3. We're going off the record.

(Whereupon, a brief recess was taken off the record.)

THE VIDEOGRAPHER: The time is 2:18. This begins media unit No. 4. We're back on the record.

BY MR. TRISCHLER:
Q. Early on in the deposition, Dr. Song, we talked about your understanding of how the medical monitoring class was to be defined and you published it on page 4 of your report that I think we marked as Exhibit 4. Do you remember that?
A. Let me go to that page in the report. Thank you for putting it up on the screen.
Q. If you look at the last sentence of the first paragraph that appears there, what you wrote was that:
"The medical monitoring classes are defined as all persons who consumed the defendants Valsartan-containing drugs containing NDMA or NDEA

and who have accumulated sufficient quantities of lifetime cumulative exposure to require medical monitoring," and the you go on.

Correct?

A. Those are the words that you just read.

Q. As a physician, how do you determine if a patient had met a lifetime cumulative exposure that is met for NDMA or NDEA?

MR. MIGLIACCIO: Objection. Asked and answered.

THE WITNESS: I do recall that we talked about this earlier today, but to answer your question again anew, first of all, I defer to our oncologist expert with regard to every component of the medical monitoring program and every component of class definition, as well as other colleagues in the case, such as counsel, and as far as my knowledge is at the moment on this case, this proposed class has not been certified and the accumulated sufficient quantities of lifetime cumulative exposure has been proposed, but not yet finalized. So it is not my place in this case to think through this definition of class or to opine on the definition of class because No. 1, it is not what I was retained to do, and No. 2, I would defer all substantive questions about the monitoring

program and about the class to our subspecialty colleagues and counsel, and my expertise that was in this -- that was asked to be applied to this case is with regard to the pricing of medical services.

BY MR. TRISCHLER:

Q. You wrote this report, including the phrase that we highlighted on page and what we're looking at right now. Correct?

A. Correct, and I just characterized the meaning of what I wrote for you.

Q. And all I'm asking is whether you as a physician have the ability to determine if a given patient has exceeded what you write as a lifetime cumulative exposure to NDMA or NDEA. Do you have that ability?

MR. MIGLIACCIO: Same objection.

THE WITNESS: There are various analytic skills and abilities, if you will, that I've been trained to practice in my professional life as a physician and a health economist. I have not been asked to apply any of those abilities to this case, and I have not been asked to examine the accumulated risk or the cumulative exposure. I've not been asked to examine that data to make a formulation. Those,

as I understand, are aspects of this case performed by other specialists, other technical persons.

BY MR. TRISCHLER:

Q. Are nitrosamines excreted from the body after exposure?

MR. MIGLIACCIO: Objection. Vague.

THE WITNESS: Analogous to your previous questions with the vague aspects of the definition, you've used exposure many times, and I'm still struggling with what you mean about exposure. You have yet to define exposure in your questions regarding exposure. Is it exposure from contaminated Valsartan, which is the subject matter of this case, or is it exposure as you inferred earlier on from other sources? They're not the same concept, in my view, because this matter pertains to carcinogens in a contaminated drug. So what do you mean by "exposure" in that first question?

BY MR. TRISCHLER:

Q. Are -- those are all good questions. Hopefully, we can get an answer to at least one of them. Are nitrosamines, such as NDMA or NDEA, that are ingested excreted from the body after ingestion?

A. Do you mean ingestion through a small molecule drug, like a tablet, a pill, or a capsule?

Q. That would be one way, or how about in our food or how about in our water?

A. Okay, and what amount of ingestion are you referring to in this question?

Q. It doesn't matter. You tell me. I'm only asking you if you know, are a portion of the nitrosamines that an individual ingests, are they excreted or eliminated after the exposure?

A. My training to date as a physician of social scientist is outside the scope of that question and certainly my work in this case falls outside the scope of that question. I do not have enough training at a biochemical or physiological level in terms of pharmacology to be able to offer you an answer on that.

Q. Do you know one way or the other whether all of the members of this proposed class were exposed to the same levels of NDMA or NDEA?

A. Again, I was not asked to think about that question because that is unrelated to the pricing of medical services and the common methodology for arriving at pricing. Again, in an effort to be helpful to you, the materials we've

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already talked about in this case, as we've already discussed this morning, propose a point system for arriving at a threshold of exposure. The very presence of a point system conveys to me or connotes to me that exposures can differ across people, but that is not what I was asked to assess in this case.

Q. If exposures to nitrosamines can vary by patient, whether depending upon diet, lifestyle, dose or duration, or any other factor, would you agree with me that it would be difficult or impossible to determine which patients met their lifetime threshold for NDMA or NDEA specifically from taking affected Valsartan as opposed to some other source?

MR. MIGLIACCIO: Objection. Incomplete hypothetical. Vague. Compound.

THE WITNESS: I'm trying my best to give you an answer, sir, but I do not have enough by biochemistry, physiologic, or pharmacologic training to answer that question.

BY MR. TRISCHLER:

Q. We talked before about the class plaintiffs. Do you recall having a brief discussion about that?

A. Yes, I believe on several occasions

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today we've talked about that subject.

Q. Sure. I asked you specifically if you reviewed the medical records for any of the medical monitoring class plaintiffs, and you said you had not. Right?

A. That's correct.

Q. And you said that you didn't recall offhand the names of any the medical monitoring plaintiffs and never spoken to any?

A. That is also what I said earlier, yes.

Q. I'll represent to you that one of the plaintiffs in this litigation is a gentleman by the name John Judson, J-U-D-S-O-N. Does that name ring a bell to you?

A. It does not because of what we just talked about.

Q. And I'd like you to assume the following facts for purposes of my next series of questions. I'd like you to assume that Mr. Judson is a 64-year-old gentleman with a family history of colon and liver cancer, and because of that family history of cancer, Mr. Judson has been undergoing colonoscopies every three years since 2008, long before he was ever exposed to any recalled Valsartan. And during one of those early screenings, I'd like

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you to assume that one of the colonoscopies that Mr. Judson received was positive for nonmalignant colon polyps, and as a result, he's now under doctors orders and recommendations to get a colon screen every three years. Are you with me so far?

A. I'm taking notes as you speak about this patient.

Q. Good. I'd also like you to assume that Mr. Judson's treating physicians have sent him for regular prostate cancer screens in the form of PSA tests since 2004, long before he ever used any recalled Valsartan. Do you understand those facts as I've asked you to assume them?

A. As you've stated in that way, yes, I believe I understand them.

Q. Based on the history as I have reported it to you, would you agree with me that Mr. Judson is a patient who would have received those colonoscopies and those PSA screenings regardless of any exposure to NDMA or NDEA?

A. You've given me a clinical vignette, which is the first time that I've been presented with a detailed clinical vignette to think through for my work in this case. I have not to date been asked to think through clinical vignettes such as this with an

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individual patient, again, because the scope of my work pertains to medical pricing or pricing of medical services, which is unrelated and uncorrelated to clinical variations across patients, and because you have given me this clinical vignette, it is clear to me that the right person to opine on the appropriateness of screening for this is or any such patient in a scenario like this would be an oncologist, would be someone with expertise in cancer screening and training in oncology more than I have received. So I do not feel comfortable answering your question as it is stated here for this particular patient. I'm sure there are other aspects to this patient's care that an oncologist would want to know outside of what you've provided in the anecdote right now.

Q. It's a shame because I was really hoping to get a responsive answer to my question. Let me try something different.

I'm sure that you would agree with me that in a monitoring program, that we should include a program only charges for procedures that are directly related to or necessitated by exposure to NDMA or NDEA; wouldn't you agree?

A. Well, the common methodology for

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applying the pricing of medical services could pertain to any service, and after I've described to you how prices are determined, you can take that common methodology and apply it to any given service that might be part of a potential monitoring program.

As I think I just said a few minutes ago, I defer all substantive questions about what services are in the monitoring program and who is in the class to the other experts in this case who have been retained, as far as I know, to opine on matter such as those because that question is not part of my work in this case.

Q. Then I don't understand what your work in this case is because I asked you specifically about monetizing the monitoring program, which your own retention agreement, Exhibit 2, says you were retained to do.

A. Yes, and I just explained --

Q. So what I asked you is when you go about monetizing a monitoring program, are you going to include in that program costs for procedures that are not directly related to exposure to NDMA or NDEA?

A. Thank you for further clarifying your question. I would apply the common methodology for deriving the pricing of medical services to any

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monitoring program that's certified and finalized in a case such as this, and in the certification or the finalization of such monitoring program, your question I imagine will be addressed either by the factfinder or a judge and jury or other expert services. Therefore, I disagree with your prior characterization because I have answered your question and quite specifically too. Whether it's commercial prices, Medicare prices, Medicaid prices, we can talk about the pricing of medical services, which is the subject of my report, one can apply the common methodology of pricing to any service. You're asking about the appropriateness of services. You're asking about the quantities in price times quantity equals spending, and I'm again just emphasizing my report and my scope of work in this case is about prices. Price times quantity equals spending. And I respect your questions about quantities, but quantities are the domain of the other experts, and therefore, I'm happy to answer any questions about prices and I'm happy to say again here you can apply a common methodology around pricing towards any quantities that end up in a final monitoring program. But the content of the monitoring program just as the members of a final certified class are not part of my

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report here.

Q. You're not answering my question, sir. I'm asking you about how you are going to monetize the program, which you told me is part of your work, so I'm asking you, when you sit down to monetize this monitoring program, are you going to include charges for screening procedures that are unrelated to exposure to NDMA or NDEA; yes or no?

A. I first have to make a correction on your question, sir. You said charges, and clearly in my report as I emphasize in the initial paragraph and throughout the report, we're talking about the prices of medical care in the U.S. Prices are different from charges in a very explicit way that I discuss at length in my report. So if I may correct your question, you're asking about prices and how those prices are applied to a monitoring program, and again, my answer is prices are applied in a common methodology that I've described to any components of a final certified monitoring program. You are asking about what should be in the final monitoring program. Under what conditions, as I understand your question, would it be appropriate for a service to have that pricing applied, and I'm again clearly delineating the subject of my work for this report, which is

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around the pricing of services from the determination of what should be priced, what should be in the monitoring program, whom should receive the monitoring program. Those are all incredibly important questions, but they were not what I was asked to work on. To my understanding, other experts have opined on such questions as those, so I would refer you to them.

Q. Based on the assumed facts that I provided to you, Mr. Judson is undergoing a colonoscopy every three years regardless of his exposure to NDMA or NDEA. Understand? I'm asking you if you understand those assumed facts.

A. Okay, I'm assuming the facts as you've asked me to, yes.

Q. And you understand that he's been receiving regular PSA screening for prostate cancer before he ever took any Valsartan that may or may not have contained nitrosamine impurities. Do you understand that?

A. As a primary care physician, I understand what you're saying about this patient.

Q. So including the costs of PSA screens and colonoscopies for patients like Mr. Judson in the class would result in a windfall, would it not, since

those procedures are ones that he is undergoing irregardless of his exposure to NDMA or NDEA?

MR. MIGLIACCIO: Objection to form.

THE WITNESS: I'm so sorry, I have to do this again, but I have to correct your question because --

BY MR. TRISCHLER:

Q. Your job is not to correct a question, sir, your job is to answer it.

A. Your question then doesn't make sense to me because you asked about costs, and clearly my report explains how prices differ from costs. I think you mean prices. I'm trying to honestly help you ask the question in a way --

Q. Well, I'm not as smart as you, so give me all the help I need, Doctor. Don't be condescending.

MR. MIGLIACCIO: Objection. Objection to this harassing colloquy. Let him -- let him ask you to clarify his question.

THE WITNESS: I'm merely stating when you ask about costs, you're asking about a different financial entity, and I devote an entire paragraph, if not more, than that. If you're asking about

prices, that's a different entity. I think you would agree with me that this case is important for a lot of people, and we need to get the specifics of the words and the definitions right. I think you're asking about prices. That's No. 1, and my report pertains to the pricing of medical services. You then asked about windfall. I'm confused about that. What do you mean by "windfall"? Can you quantify "windfall" and can you characterize "windfall"?

BY MR. TRISCHLER:

Q. Do you want me to look it up in a dictionary and give you a dictionary definition of the word? With your years of higher education, you're telling this jury you don't understand what the word "windfall" means? I will look it up.

A. Look, I won't accuse you of condescension, but I'm just looking for some help of the magnitude of windfall. What do you mean? You haven't stated who is receiving a monetary amount of how much. So with those two big variables lingering, I don't know how to judge what you mean by "windfall."

Q. I'm going to give you a dictionary definition since you don't understand what that term

means. Just bear with me.

A. Okay, thank you.

Q. A piece of unexpected good fortune. Does that help?

A. Okay, what do you mean by your question then? You asked me do you not think --

(Whereupon, the requested portion of the record was read by the reporter.)

MR. MIGLIACCIO: Same objection and also to the extent it calls for a legal conclusion.

THE WITNESS: Thank you for rereading it. I'm going to assume that by "windfall" you mean an amount that goes to the patient. You're challenging -- you're asking if a service ought to belong in a monitoring program, and if that is your challenge, I think you should present that challenge to the factfinder, the judge, jury, our oncology experts, and others to argue that under these particular circumstances or for this patient, this service or that service ought not to be in a monitoring program. I have not restricted you from doing that in any way, nor have I inferred your preference for doing so. All I've said is that after

that process take place and after the final monitoring program is determined, the application of prices to this final program after you resolve the issues that you're talking about has a common methodology and is what my report addresses. I do think that answers your question, and in part, it does say that your question remains outside the scope of what I was retained to opine on. That remains true, sir, and I'm saying this respectfully.

BY MR. TRISCHLER:

Q. Let's assume the final class is decided to consist of 100 people for simplicity sake, okay?

A. Okay.

Q. And that the -- those 100 people include Mr. Judson with his prior history of -- with his family history of colon and liver cancer and with his doctor putting him on a regular screening regimen before he ever started taking Valsartan. Are you with me?

A. Yes, sir, please go ahead.

Q. And then let's assume that since he's in the class, my question is: When you use your common methodology to monetize the monitoring program, are you going to include the cost for his colonoscopies

and his PSA tests or do you have a methodology by which to exclude procedures that are done irregardless of exposure to NDMA or NDEA?

A. If in the final certification of a monitoring program the services that you just asked about for this patient that you just asked about end up being certified as part of the monitoring program, then you would take a common methodology such as one that I proposed for applying the prices of services to quantities and apply those prices to the quantities that you're explicitly addressing here. If, however, a factfinder, a judge, a jury, a decisionmaker decides that for a patient in a particular clinical situation a given service should not be part of the monitoring program, then of course you would not apply the prices that I am proposing in my report or the common methodology for applying prices in my report to that quantity of services. That is what we've been returning to time and time again, sir, prices times quantities equals spending. My report addresses the pricing of medical services. You've asked many questions about quantities, and I've reemphasized the importance of your questions about quantities, but they're not the subject of my work in this case, and they're better answered, at

least for some of your questions, by others, such as an oncology expert. It's unrelated to the pricing of medical services because the application of the common methodology for pricing to any medical services that are potentially in a monitoring program is common. That application is common. There's a common methodology for doing so. That's what my report pertains to.

Q. So I think if I follow what you're saying, your common pricing methodology would not exclude the prices paid for services like Mr. Judson's. That would be the responsibility of someone else to exclude those from the program?

MR. MIGLIACCIO: Objection. Misstates testimony. Assumes facts not in evidence.

THE WITNESS: I don't agree entirely with your characterization, but I agree partly with it, so I would just reformulate what you said as whatever services end up being certified in a medical monitoring program, the pricing of those services has a common methodology that I'm discussing in this report, and that is the scope of my work in this case to date.

BY MR. TRISCHLER:

Q. Right, and your common pricing methodology, as you've called it, does not have the ability to distinguish between screening procedures related to NDMA or screening procedures that might be necessitated by some other medical cause or condition?

MR. MIGLIACCIO: Objection. Calls -- assumes facts not in evidence.

THE WITNESS: Thank you for this question, which I think for the first time actually addresses something germane to my report, and that is the pricing of medical services in our U.S. healthcare system, meaning the price for every CPT code of a fee schedule, whether that's a Medicare or commercial insurance or Medicaid, is agnostic to patient level variation to clinician level variation and who orders the CPT code or who orders the service or who bills the CPT code, who has received the CPT code, or who has received the clinical service, under what circumstances those services were delivered to the patients. All of those factors are unrelated to the pricing of medical services in the U.S. I hope that helps clarify things in your question.

BY MR. TRISCHLER:

Q. What would help clarify is a yes or no answer to my question, but I've sort of given up the idea of getting one of those. I'll ask another question.

Your common pricing method does not factor in whether any of the healthcare services are related to NDMA exposure or unrelated to NDMA exposure. It's for someone else to do that. That's what you keep telling me.

MR. MIGLIACCIO: Objection. Assumes facts not in evidence. Calls for a legal conclusion.

THE WITNESS: If you look at how the prices of medical services are derived in the U.S. healthcare system, they're derived not on the things you just listed. In fact, as my report explains, and to be very concrete here, sir, every physician service in the physician fee schedule, which across all payors tends to be based on the Medicare physician fee schedule, is determined by a component of physician work relative to value units, a component of practice expense, practice expense relative to value units, and a component of malpractice risk relative to value units. That system for determining physician prices or for prices of medical services in the U.S. dates back to the

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1980s, and in neither or in none of those three components that makes up or comprises the price of a medical service in this country do you find the factors that you just listed.

So it is not a subjective choice that I'm making here as a health economist in demonstrating to you how prices are determined for medical services. I'm following a precedent that is decades old and a precedent that exists across payors in the country for a common methodology of deriving prices. There are three components to every price in the fee schedule, as I just summarized for you.

BY MR. TRISCHLER:

Q. So you monetized this monitoring program. It is irrelevant to your calculation of whether the services were necessitated by NDMA exposure or some other medical circumstance?

MR. MIGLIACCIO: Objection. Misstates testimony. Calls for a legal conclusion.

THE WITNESS: The services that ought to belong in a potential medical monitoring program are in the domain of other experts and other people in this case. They're not irrelevant to the case. I've just stated many times whatever ends up being

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certified or determined to be part of a final monitoring program would be respected for -- by a physician economist expert like me in thinking about how to price those services, but the determination of what belongs in a medical monitoring program is not within the scope of what I've been asked to do in this case, nor are your factors around appropriateness germane to how medical prices of healthcare services are derived in the U.S. healthcare system across payors in a common way.

BY MR. TRISCHLER:

Q. You said that the services that are to be included in the monitoring program are the domain experts. Aren't they the domain treating physicians? Don't they have a say?

MR. MIGLIACCIO: Objection. Vague.

THE WITNESS: We'll we've talked about screening guidelines so much today, and even as physicians follow guidelines, at least in my own experience as a general primary care physician, we talk about and we decide with patients in certain situations what the best course of action is. Your question is so general that I don't know possibly how it applies to the pricing of medical services, which

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I don't think it does, and just as a general clinical matter, doctors and patients discuss what the next step in the management of a clinical condition is, but that is unrelated to how one would price a potential monitoring program and unrelated to how I would treat a final program, a monitoring program, that's certified.

BY MR. TRISCHLER:

Q. Did I ask you if it was related to that? I simply asked you to respond to a comment that you made where you said that the services of a monitoring program are the domain of the experts. All I asked you was do the treating physicians in these patients have a role to play in that. You made the comment. I'm asking you to follow up on that.

A. Yes, but there's a big difference there, sir. The components of a potential monitoring program are, to my understanding, determined as part of this litigation. Correct? Perhaps as not an attorney, I have misspoken on that. To my understanding, the potential monitoring program that might arise from this litigation will be determined by factfinders and witnesses and a judge or jury in this case. You're asking me about once a potential

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monitoring program exists, do patients or physicians have a role at all in what happens afterwards, and to that very general question, I'm giving you an appropriately general answer, which is well, yes, in my experience as a primary care physician, patients and physicians discuss what the next best step in the management of a clinical condition is. I don't see how that's inconsistent with anything I've said.

Q. All I'm trying to find out is if the treater has a role to play. If you agree that he does, then I guess we're done with that issue.

A. I'm sorry, was there a question in that statement there?

Q. Yes, there was. Does the treater have a role to play in deciding what screening procedures a given patient ought to receive and when?

MR. MIGLIACCIO: Same objections.

THE WITNESS: With respect, didn't I -- let me rephrase. With respect, I just answered that question. I would just refer you back to my answer immediately preceding this one.

BY MR. TRISCHLER:

Q. Well, with respect, I don't remember the answer, so can you answer the question, please?

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MR. MIGLIACCIO: Can the reporter read it back, if you don't remember it?
MR. TRISCHLER: I'm asking the witness to answer the question.
MR. MIGLIACCIO: Objection. He's asked and answered it.

(Whereupon, the requested portion of the record was read by the reporter.)

THE WITNESS: So my previous answer to you in an effort to summarize it so we don't have to track that down and read it out again was simply that the components of a monitoring program, as far as I understand, will be determined by this litigation process and the people within this litigation process once such the monitoring program is certified.

BY MR. TRISCHLER:
Q. I didn't ask you about the components of the monitoring program, sir.
A. What happens afterwards out in the real world when such a monitoring program is in existence could certainly be influenced by what physicians and patients decide together. That is such a generality.

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You're basically asking me do doctors and patients have a role to play in the healthcare that's rendered, and as a general matter and as a primary care physician, the answer is doctors and patients discuss various aspects of care in how to proceed to the next step of a clinical management of a condition, and that is the best answer as a physician that I can give you and still it remains outside the scope of what my report focuses on.

BY MR. TRISCHLER:
Q. Have you ever done before what you were asked to do in this case?
A. What do you mean by that, sir?
Q. Have you ever monetized a medical monitoring program?
MR. MIGLIACCIO: Objection. Misstates.
THE WITNESS: I probably answered this earlier today too when you asked me about what I did in those other cases for which I've been retained as an expert witness, but to answer this anew here, I have been asked to opine on the appropriateness of medical charges and prices. So, that part I think has a natural relation to the pricing of medical services, so that is related to the focus of my

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report here.

BY MR. TRISCHLER:
Q. I didn't ask you if you've done anything that's related. My question is: Have you ever monetized a medical monitoring program before?
MR. MIGLIACCIO: Objection.
THE WITNESS: I was just going to add that the appropriateness of charges and prices in those other cases did not pertain to a proposed monitoring program. They pertained to medical services and medical services that may even overlap with a final monitoring program in this case, but they did not pertain specifically to a medical monitoring program.

BY MR. TRISCHLER:
Q. So have you ever monetized a medical monitoring program before?
A. I have in my research, much of which is cited in the report, applied the prices of medical services to a whole host of medical services, both preventive and diagnostic and therapeutic. I will just give you one concrete example. There is a 2019 Journal of American Medical Association or JAMA paper

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on the pricing of medical services. It's two-page paper with an appendix table. I have, in your words, monetized, but again, in my definition, priced a number of medical services clearly using 2016 commercial insurer data in a large table in that appendix, and you know, that describes what you're asking about, so there's an example of what I've done.
Q. Does that paper talk about a medical monitoring program established for a class of unknown asymptomatic individuals who are going to be screened for cancer or medical conditions?
MR. MIGLIACCIO: Objection. Assumes -- to the form of the question.
THE WITNESS: Not specifically to a medical monitoring program.

BY MR. TRISCHLER:
Q. Let me see if I can ask the question maybe for a fifth time and get an answer. Have you ever monetized a medical monitoring program before you were asked to do so in this case?
A. Let me answer more narrowly. For the purposes of litigation as an expert witness, I have not in the other cases that we talked about at the

beginning of the day conducted an exercise to demonstrate the common methodology in applying the prices of medical services to a potential monitoring program. However, the subject of my work in those cases did pertain to the prices of medical services.

Q. Have you ever monetized a medical monitoring program before?

MR. MIGLIACCIO: Objection. Asked and answered.

THE WITNESS: Please refer do my previous answer, sir.

BY MR. TRISCHLER:

Q. Have you ever monetized a medical monitoring program before?

MR. MIGLIACCIO: He answered your question, counsel.

MR. TRISCHLER: No, he has not.

MR. MIGLIACCIO: Yes. He has.

MR. TRISCHLER: He's avoided it with nonresponsive information --

MR. MIGLIACCIO: No, he has not.

MR. TRISCHLER: Nick, don't interrupt me, please. I'm entitled to an answer to my question.

MR. MIGLIACCIO: Don't interrupt me. You're starting to badger him. I would advise you to move on to your next question, counsel.

BY MR. TRISCHLER:

Q. Have you ever monetized a medical monitoring program at any point before you were asked to do so in this litigation?

MR. MIGLIACCIO: Objection. Asked and answered. Move on to your next question, counsel.

MR. TRISCHLER: I'm not moving on. I'm waiting for an answer to my question. If you're going to instruct him not to answer, Nick, let me know because I'll be happy to take it up.

MR. MIGLIACCIO: You know what, he's given you the answer to your question many, many times.

MR. TRISCHLER: I'm going to ask it again, and you can either allow him to answer or you can instruct him not to answer.

MR. MIGLIACCIO: I'm allowing him to answer, but he's given you your answer. I'm not instructing him not to answer any question. You've asked your question. You've gotten your answer. You keep asking it. You know, we can be here until 7:00

or I don't know how much time we have left if you want to keep asking the same question and get the same answer. That's your choice in the time that you wish to use that remains in the deposition.

BY MR. TRISCHLER:

Q. Prior to this litigation, have you ever monetized a medical monitoring program?

A. Let me reform late my answer for you. Some questions simply, as I'm sure you know in your wealth of experience, sir, don't have a simply yes or no question because the real world is more complicated than that, and I have explained to you in detail the analogous complexity here. I have in both my research -- I have just cited for you a paper in 2019 in JAMA, as well as in my prior work as an expert witness thought through and used the application of a common methodology to attach the prices of medical services to the CPT codes that are the medical services. That work is pertinent and, in my view, relevant and related to the work of applying prices to a potential monitoring program here.

And then I, in addition, said as for a proposed medical monitoring program in the other cases that we've discussed, I have not done a

replication of exactly this report for those, but the subject matter of medical prices is related, and I think a nuanced answer like that, which recognizes the complexity of the world and potentially an academic's life in writing papers and providing expert testimony, is reasonable, sir. Even if your preference is for a simple yes or no answer, I can only do my best in giving you what I think is the best, most truthful answer.

Q. In your other work, particularly your other litigation work, have been involved in looking at the reasonableness and necessity of the prices for medical services. Correct?

A. Reasonableness and fairness, not necessity. Reasonableness and fairness.

Q. In your common pricing methodology, do you concern yourself with the necessity of the services?

A. Again, those cases were about reasonableness and fairness --

Q. I'm not asking you those cases.

A. To my understanding, you're asking me --

Q. Not now. I'm allowed to ask you different questions. Do you understand?

A. I do, but you're also asking a question

immediately off of another one.
Q. So what?
A. Sir, you were simply not clear in changing subjects. That's all I'm saying. Now that I've understood that you changed subjects, I'm happy to start over. If you wouldn't mind just repeating your question, please.
Q. In your common pricing methodology that you hope to employ, do you concern yourself with the necessity of the medical services that are part of this program?
A. Thank you for clarifying that question. I concern myself with the application of the common methodology to whatever the services in the final monitoring program end up being, but necessity was not part of what I was asked to opine on, and therefore, my common methodology is agnostic to how you're asking about necessity. Necessity is inferred -- it's implied by the existence of a service in a final certified monitoring program. I think it's reasonable for us to think of it that way prior to a such a monitoring program being finalized and certified. Therefore, necessity is not irrelevant here. I'm just saying that the common methodology for applying prices is unrelated to the

way you're phrasing "necessity."
Q. So Michael Rives, do you know who that is, R-I-V-E-S?
A. Off the top of my head, I do not know that name, sir.
Q. Mr. Rives is one of the plaintiffs in this action; did you know that?
A. No, I did not prior to you telling me just now.
Q. Did you know that he undergoes regular endoscopies based on the advice of his physician because due to come underlying medical conditions from which he suffers?
MR. MIGLIACCIO: Objection.
THE WITNESS: Given what we have established, I have not spoken to any of the plaintiffs, nor reviewed their medical records. The answer is no.

BY MR. TRISCHLER:
Q. Since Mr. Rives undergoes regular endoscopies for reasons totally unrelated to NDMA or NDEA exposure, including the price of that service in a medical monitoring program would not be necessary; would it?

A. That is up to the factfinder and the decisionmaker about what belongs in a medical monitoring program at the end of the day.
Q. Your common cost methodology would not exclude procedures that are -- that have been covered by -- or that the patient has received for reasons unrelated to NDMA or NDEA exposure?
MR. MIGLIACCIO: Objection. Assumes facts not in evidence.
THE WITNESS: You're supporting my argument here, sir. A common methodology is common because it is applicable across situations that may have some differences, and I've explained several times that applying the prices of medical services to those medical services can be done in a common fashion, and you are again asking about the appropriateness of a certain service in a certain patient's case on a monitoring program, and whatever the monitoring program ends up being at the end of the day is what you can apply in a common methodological way the pricing of medical services. We've talked about this several times, and analogous to your prior anecdote about the 64-year-old man, I'm thinking through this second anecdote in a very similar fashion.

BY MR. TRISCHLER:
Q. Even if a medical monitoring program were to be approved and -- or certified and if even all of the foundations of that program that you discuss in your report were included as part of it, I assume that you would agree with me that every patient who's included in that program would still need to work with his or her treating physician and make an independent evaluation whether the procedures were medically necessary for that patient or whether they were procedures that -- where the risks might outweigh the benefits for that particular patient. Can we agree on that?
MR. MIGLIACCIO: Objection. Incomplete hypothetical. Compound.
THE WITNESS: I have answered that question for you a little while ago when I said after a medical monitoring program is finalized and certified, what happens to it in the real world given its existence between doctors and patients, I had as a general clinical matter as a primary care physician said to you that patients and physicians have a role to play in determining what the patient receives the next step in management of a clinical condition, and

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I think you've just asked about that again, so I'm referring back to that response.

BY MR. TRISCHLER:

Q. So you have told me on several occasions that the scope of your report is limited to monetizing a medical monitoring program. Correct?

A. The pricing of services in a proposed medical monitoring program, yes.

Q. And you have not formed any opinions as an expert in this case, other than your opinion that a common pricing methodology can be applied to a medical monitoring program. Fair to say?

A. That is fair to say, sir.

Q. So it's fair to say that your opinions in this case are limited to that common pricing methodology?

A. That is fair to say, and that is what I've been trying to say for several hours today. I'm very grateful for your arriving at that summary conclusion.

Q. I'm a little slow, so you got to bear with me.

A. I agree with that statement.

Q. You were not retained to offer any

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opinions on liability on this case. Correct?

A. That is correct, sir.

Q. And you do not intend to offer any opinions on liabilities issues in this case. Is that correct?

A. At the moment, I have no such intention.

Q. It is not your opinion that any of the defendants in this case violated any good manufacturing practices; is it?

MR. MIGLIACCIO: Objection. Outside the scope.

THE WITNESS: I have not considered that question before, nor was I retained to think about that question. This is the first time I'm hearing that question, so I don't have an answer for you off the top of my head here.

BY MR. TRISCHLER:

Q. But you don't intend to offer an opinion that the defendants in this case have violated good manufacturing practices; do you?

A. I have not been asked to render an opinion. I don't intend to render such an opinion on my own.

Q. And you don't intend to offer the

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opinion that any of the Valsartan in this case was adulterated?

A. Again, I have not been asked to render an opinion on that, and on my own accord, I don't intend to render or offer an opinion on that question.

Q. You don't intend to offer the opinion that any of the Valsartan in this case was misbranded; do you?

A. Similar response to you. Happy to repeat it. I was not asked to opine on that question, and at the moment, on my own accord, I do not intend to offer an opinion on that question.

Q. And you do not intend to offer the opinion that the defendants in this case violated any legal duties or obligations of any kind. Is that fair to say?

MR. MIGLIACCIO: Objection. Calls for a legal conclusion. Outside the scope.

THE WITNESS: Just to be precise again, sir, I don't mean to drag on. I have not been asked to render an opinion on that question, and in my own accord, I do not at the moment intend to offer an opinion on that question.

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BY MR. TRISCHLER:

Q. Do you intend to offer any opinions to suggest that the defendants violated any express or implied warranties?

MR. MIGLIACCIO: Objection. Calls for a legal conclusion.

THE WITNESS: Similarly, I was not retained to opine on that question, and likewise, I do not intend to offer an opinion on that question.

BY MR. TRISCHLER:

Q. Do you intend to offer any opinion suggesting that any of the defendants in this case made any false representations or omissions?

MR. MIGLIACCIO: Objection. Calls for a legal conclusion.

THE WITNESS: Again, I was not retained to opine on that question, and sitting here today at this moment, I have no intention on my own of providing an opinion on that question.

BY MR. TRISCHLER:

Q. Do you intend to offer an opinion that any of the defendants in this case engaged in any deceptive or unfair practices?

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MR. MIGLIACCIO: Objection. Calls for a legal conclusion.

THE WITNESS: My apologies for the repetition. I was not retained to opine on that question and do not intend to at the moment render an opinion on that question on my own.

BY MR. TRISCHLER:

Q. Do you intend to offer an opinion that any of the defendants in this case did anything wrong at all?

MR. MIGLIACCIO: Objection. Calls for a legal conclusion -- to the extent it calls for a legal conclusion.

THE WITNESS: Again, for that question and especially for such a general question, I was not asked to render an opinion on that issue and on my own accord, sitting here today, do not intend to render an opinion with respect to that question.

BY MR. TRISCHLER:

Q. Do you have an opinion as to whether the generic Valsartan produced by the defendants in this litigation was bioequivalent to the brand name Valsartan products?

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A. Since it was outside the scope of what I was asked to do and I have not spent time looking into that question, I do not have an opinion for you on that question here today.

Q. And I trust that you do not intend to offer an opinion at any trial or subsequent hearing in this matter?

A. As a general matter, I don't know of what other questions I may be asked to opine on in the future by counsel. Sitting here today, I have not been asked to opine on that question, and on my own afford left to myself, I do not intend in the future to offer an opinion on that question.

Q. Is it your opinion that the Valsartan-containing medications produced by the defendants in this litigation was worthless?

MR. MIGLIACCIO: Objection to the extent it calls for a legal conclusion.

THE WITNESS: I don't want to prolong an unnecessary or an unrelated part of our discussion. When you say, "worthless," what do you mean, sir?

BY MR. TRISCHLER:

Q. Of no value whatsoever.

A. Okay, I was not asked to render an

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opinion on that question, and sitting here today, under my own accord, I do not plan to offer an opinion on that question.

Q. You've not -- you already told me that you have not looked any of the medical records for any of the class plaintiffs, nor reviewed their depositions or spoken to any of them. Correct?

A. Correct, I did tell you that before.

Q. So I take it that it is not your opinion that the plaintiffs and the proposed class members in this case suffered a common injury?

MR. MIGLIACCIO: Objection. Calls for a legal conclusion.

THE WITNESS: You have not asked me a yes or no question on an issue I was not retained to opine on. That question is unrelated to the pricing of medical services for a potential monitoring program, so I do not have an opinion one way or the other on that question as it pertains to the pricing of medical service.

BY MR. TRISCHLER:

Q. Should I infer from that that you do not intend to offer an opinion suggesting that the plaintiffs in this action or the proposed class

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members have suffered some common injury?

MR. MIGLIACCIO: Objection to the extent that it calls for a legal conclusion.

THE WITNESS: Well, again, at the moment, I have not been asked to render an opinion on that. As far as the future, I don't know what I'll be asked to opine on in this case, so I cannot say one way or the other. My report focuses on common methodology. You're asking about common injuring. I'm interpreting those two things as different aspects of this case, and given that preface, sitting here today, on my own, I do not intend to offer an opinion on the injury portion of this case. That does not preclude what I may be asked to do in the future. Go ahead.

BY MR. TRISCHLER:

Q. Whether through testing data, test reports, or other materials, have you seen any evidence that any of the plaintiffs to this action have suffered a cellular or genetic injury from exposure to NDMA or NDEA?

MR. MIGLIACCIO: Objection to form. To the extent it calls for a legal conclusion.

THE WITNESS: The assessment of cellular

or genetic injury requires expertise that not only was I not asked to provide in this case, but also exceeds the scope of my general clinical practice as a primary care physician.

BY MR. TRISCHLER:

Q. Since the issue of a cellular or genetic injury is something that exceeds your expertise, I take it that you do not intend to offer an opinion that the plaintiffs and the proposed class members in this case suffered from common cellular or genetic injury?

MR. MIGLIACCIO: Same objection.

THE WITNESS: I have not been retained to do so to date, and on my own accord, I do not intend to provide an opinion for that question.

BY MR. TRISCHLER:

Q. I'm sorry. It's fairly clear to me today that your role is limited to monetizing a medical monitoring program, and that being the case, I take it that you do not have any opinion as to whether the plaintiffs and the proposed class members in this case require a common medical monitoring program. Agreed?

MR. MIGLIACCIO: Objection. Misstates and you can answer.

THE WITNESS: Okay, as I've said several times before, the scope of my work in this case thus far as reflected in my report focuses on the pricing of medical services for a proposed medical monitoring program, and any substantive opinions outside of that scope I would in general say that I am not rendering an opinion on at the moment.

BY MR. TRISCHLER:

Q. And I take it that you also do not intend to offer an opinion that the plaintiffs and the proposed class members in this case have suffered some sort of economic injury. Correct?

MR. MIGLIACCIO: Objection and to the extent it calls for a legal conclusion.

THE WITNESS: Similar to my answer before about cellular injury or genetic, I believe that's how you phrased the earlier question, I was not asked to opine on that question to date, and I do not have any intention to, at the moment on my own, to provide a separate opinion from this report on that question.

BY MR. TRISCHLER:

Q. To estimate and project the required spending for a medical monitoring program, do you agree that one would need to know the size and composition of the patient population undergoing monitoring?

A. I've said -- I've said so in several ways already today. Prices times quantity equals spending, and I've explained that quantities are derived from both what is in a monitoring program and who is in a monitoring program. So that analogously reflects what you just said. So your characterization of what information is needed for quantities I generally agree with here, and prices times those quantities would give you spending or estimated spending for a monitoring program.

Q. Just so I understand, you have not done any analysis of the size of the proposed class or who should actually be in it?

A. That is correct.

MR. MIGLIACCIO: Objection. I object to the extent it calls for a legal conclusion, but you can answer.

THE WITNESS: Thank you. That is correct. That was outside the scope of what I was

retained to opine on.

BY MR. TRISCHLER:

Q. And you're not -- and it's also outside your scope to say what services should be part of that program that might ultimately be certified?

A. I have also said this several times earlier today, yes.

Q. And in your report, I think it's at page 25, if you need to take a look at it.

A. Okay.

Q. I think you talk about actual cost of monitoring and you write something to the effect that estimating spending in a medical monitoring program requires an analysis of several key factors, including the insurer mix, site of care composition, and network status of providers. Is that true?

A. I'm just referring to the page here on the screen.

Q. Take a look. I may have given you the wrong page reference.

A. No, you were right, paragraph 39.

Q. Am I right in stating that estimating spending in a medical monitoring program requires an analysis of several key factors, including the

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insurer mix, site of care composition, and network status of providers?
A. I stand by what I've written here, yes, and that's because these are aspects of the pricing of medical services, not the quantities, but price times quantities equals spending and these are aspects that I go into detail about in my report, each of these three issues here.
Q. When we talk about insurer mix, what we're talking about there is whether someone is a Medicare recipient. Correct?
A. Yes, a Medicare beneficiary.
Q. Whether someone is a Medicaid recipient?
A. Correct.
Q. Whether someone has private insurance?
A. Correct.
Q. What deductibles and co-pays of that private insurance might be?
A. No, that pertains to cost sharing and benefit design, and it's important for us to make this distinction. The price of a medical service is a separate concept. It's a separate entity than the portion of that price that's typically assigned to patient out-of-pocket responsibility, either through a deductible co-pay or co-insurance. Here, the

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report addresses the price, the unit price. In economics, economists often talk about unit price, and the word "unit" is sort of meant to clarify this issue. Unit price is the price per unit of service with the unit price reflecting the overall price per that unit of service. Within the overall price, as you've alluded to or we know as a common matter as healthcare consumers in the U.S., there are cost sharing considerations, but insurer mix -- you just asked about insurer mix. Insurer mix is distinct from cost sharing.
Q. So when you talk about insurer mix in paragraph 39 of your report, what you're talking about is whether someone is a Medicare beneficiary, a Medicaid beneficiary, or whether they have private insurance?
A. Correct.
Q. And one of the class plaintiffs for this is case is a gentleman named Robert Fields. Do you know whether he had private insurance, whether he was a Medicare beneficiary, or a Medicaid beneficiary?
A. Because I have not reviewed their medical records, as we have previously discussed, and because I have not spoke with the plaintiffs myself firsthand, I don't I do not have that information.

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Q. What about Mr. Judson, we talked about him, do you know if he had private insurance, Medicare, or Medicaid?
A. Because I did not speak with him, nor review his medical records, no, I don't know off the top of my head.
Q. And how about Robert Kruk, K-R-U-K, the old baseball player, do you know whether he had Medicare, Medicaid, or private insurance?
A. Because I did not review their medical records, nor speak with him myself firsthand, off the top of my head, I don't know. However, I imagine it would be easily discoverable in this case, and you probably already know what insurance they had.
Q. It's probably easily discoverable. You're right about that. And there's another plaintiff in this case, a woman named Valerie Annese, A-N-N-E-S-E, do you know whether she had Medicare, Medicaid, or private insurance?
A. Similarly because I did not review her records or speak to her firsthand, I don't have that off the top of my head at the moment.
Q. So do you know the insurer mix among the class plaintiffs to this litigation?
A. Well, as I've just noted to you, I

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haven't spoken to any of the plaintiffs myself one-on-one, nor reviewed this medical records, but that's unrelated to this concept that insurer mix matters for one's calculation of expected spending, and furthermore, the final class of individuals in this case has not been certified, and so once a final class is certified, one of the elements that would be helpful for calculation of expected spending of a medical monitoring program is the insurer mix of that final certified class. And when we get to that point or if the case gets to that point, I, per this report, would support obtaining such a distribution of insurer mix. But you're asking me by person, by person, by person what insurance they had is unrelated and does not detract from the concept of that insurer mix is relevant, which I go into detail about in my report.
Q. My only question was: Do you know the insurer mix among the class plaintiff population in this case, yes or no?
MR. MIGLIACCIO: Objection. Asked and answered.
THE WITNESS: Because I have not spoken with, nor reviewed the records of each of the plaintiffs in this case and because such

individualized review of their records and their stories does not alter the uniformity or commonality for the approach for pricing medical services in this case, my answer to you is no, but it does not detract from what my report is proposing.

BY MR. TRISCHLER:

Q. What is the insurer mix nationally across the population of all Americans?

A. If you take 330 million people as the rough overall population of the United States, 55 percent of the U.S. population has private insurance within which 49 percentage points of those 55 percent of the population have employer-sponsored health insurance, generally private health insurance, leaving us 6 percent of the remaining privately insured market as being insured by non-group smaller private insurance plans, then 20 percent of the U.S. population has Medicaid and then 14 percent of the U.S. population has Medicare, then 2 percent of the U.S. population has other public programs, notably the VA, TRICARE for the military and the families, and the Indian Health Service. That leaves us with 9 percent of the U.S. population remaining which remains uninsured today.

Q. At this point, have you done anything to calculate whether the insurer mix among the class plaintiffs matches or mirrors the insurer mix nationally that you just outlined for us?

A. Given that the final class has yet to be determined or certified, it's not possible at the moment to compare the distribution of their payor mix to the national payor mix that I just identified for you.

Q. Well, you said it was easily ascertainable?

A. Is the final class determined to date?

Q. No, I doubt that it ever will be, but I asked you about the class plaintiffs, the class representative plaintiffs. Do you know what the insurer mix among the class plaintiff representatives is as opposed to the national mix that you have outlined for us?

A. You're asking about the individual person by person like you walked me through the previous exercise?

Q. Yes.

A. Because I have not spoken with, nor reviewed the records of the individual plaintiffs in this case, as we already established, I don't yet at

the moment have the insurer mix distribution for this group of plaintiffs.

Q. Now, in your report, you also state that estimating spending of a medical monitoring program requires an analysis of site of care composition. What is site of care composition? Were you able to hear my question, sir?

A. Yes, I was able to hear it. I was simply looking at the paragraph to refer you to, which goes into site of care in quite some detail.

Q. That's fine. Take your time. I thought because you weren't saying anything, I thought you didn't hear me.

A. No worries. I can give you an answer off the top of my head, but it's easier to do so with reference to the exact paragraph here. So on page 18 of my report, paragraph 29, I explain that prices vary based on site of care. To summarize what I'm explaining here in my report, within insurers, prices vary based on whether a service is delivered in the independent physician-owned office setting or broadly speaking, a facility setting. Often facility settings are HOPD or OPD settings I have explained here, which are hospital outpatient departments, HOPD, hospital outpatient departments, or simply OPD,

outpatient departments. In those types of facility settings, medical services garner both a facility fee and a professional fee, whereas in the former setting, the independent physician-owned office setting, medical services typically garner one fee as opposed to two. So when you add up the two fees in the facility setting and compare that to the one loan fee in the independent office space setting, those numbers are different, and therefore, prices differ across sites of care, and this is a common uniform reality in the pricing of medical services within Medicare and private -- with private and public insurers.

Q. At this point in time, I take it from your prior answers that you do not have any idea whether or how many of the class representative plaintiffs have undergone colonoscopies or endoscopies -- strike the question. I'll rephrase it.

Do you know how many of the class representative plaintiffs have undergone colonoscopies prior to their use of any Valsartan-containing medications?

MR. MIGLIACCIO: Objection. Vague.

THE WITNESS: By "prior to," what time

frame are you asking about?

BY MR. TRISCHLER:

Q. All I'm asking is, you know, we have a number of class representative plaintiffs. I'm simply asking you, do you know whether they've -- any of them have undergone colonoscopies, even before they ever took any recalled Valsartan?

A. In the absence of reviewing their medical records, I would not have the ability to answer that question.

Q. And I'll represent to you that there are 13 class representative plaintiffs that have been identified in this litigation. Okay?

A. Understood. Go ahead.

Q. And assume for purposes of my question of those 13, at least 11 of them have been and continue to receive colonoscopies on a regular basis in consultation with their treating physicians. Okay?

A. Okay.

Q. So of those 11, I assume you do not have any information as to the site of care for those individuals?

MR. MIGLIACCIO: I object to the extent

that it's incomplete. Incomplete hypothetical.

THE WITNESS: Because site of care is determined either through an administrative claim or a potential bill and because I have not reviewed the medical records of these individuals, I do not know at the moment the site of care for particular medical services they've incurred.

BY MR. TRISCHLER:

Q. And for those class representative plaintiffs that have private insurance, I assume you don't have information as to how many of them are receiving screening services or have received past screening services by out-of-network providers?

MR. MIGLIACCIO: Objection. Assumes facts not in evidence.

THE WITNESS: Well, similarly, out-of-network status can be determined through administrative claims data, which I've done in my prior research, or by potentially looking at a bill that a patient receives, and in the absence having reviewed individual patient records in this case so far, I do not have the data available to answer that question, but I think it's important to emphasize that there is a common methodology whether a service

is out of network or in network for a service to receive a price. The application of a pricing methodology to services is common across in network, across out of network, across Medicare, commercial, Medicaid, across HOPD site of care, across independent office site of care. These dimensions of variations that I've discussed in my report are certainly agnostic to whether I have personally reviewed any individual's medical record. There are principles of medical pricing that are common, and they can certainly applied to any member of a class or any medical service when such member's services are certified at the end of the day and done so in a common way.

BY MR. TRISCHLER:

Q. If we look at pricing on a microscale, the actual costs for monitoring procedures for any given individual will depend on a host of factors, such as their insurance program, Medicare status, site of service, and other considerations. Agreed?

A. With respect to your use of the word "cost," I will replace that with "price" because I think that's what you're talking about, not the cost -- underlying cost of delivering the service,

which I have defined in my report what cost means. So with regard to the prices, the prices do vary across insurers and within insurers in ways that I've described, and that does not detract from the common methodology of applying prices despite this variation to services that are determined to be in a monitoring program. Furthermore, I think importantly -- we should remember that in the application of a common methodology for pricing medical services, as I've discussed in my report, the data are knowable. The data for quantifying medical prices or the prices of medical services are broadly available, ascertainable, knowable, discoverable. As an example, Medicare prices are free for you to peruse online across years across sites of care. That's important for us to remember as we go through these questions because despite the variations that you're asking about, which I expounded upon in my report, that variation does not detract from the common methodology, nor does it take away from the ascertainablity of pricing data for medical services systemwide in the U.S.

THE VIDEOGRAPHER: The time is 3:47. This end media unit No. 4. We're going off the record.

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(Whereupon, a brief recess was taken off the record.)

THE VIDEOGRAPHER: The time is 4:03. This begins media unit No. 5. We're back on the record.

BY MR. TRISCHLER:

Q. Dr. Song, would you agree with me that there's abundant academic evidence that shows that the pricing information in the U.S. healthcare system is opaque?

MR. MIGLIACCIO: Objection. Vague.

THE WITNESS: Can you define what you mean by "information" there?

BY MR. TRISCHLER:

Q. Well, let me see if I can look up the definition of information if you're not --

A. Well, let me be a little more specific then. Do you mean data, fee schedules, EOBs, published reports about prices? You know, which of those sorts of things are you thinking about?

Q. Any or all of the above.

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A. So in my answer then, I'm going to be specific and precise for you. When you say, "opaque," you know, that's a very general characterization of a whole field of the study of prices of medical services. It has been commonly written and described in the popular Lay Press, as well as in academic literature, that from a patient's perspective, the prices of the medical care they receive in the U.S. often seems hard to know in advance. You might readily apply opaque to that kind of characterization. Even doctors on the frontline treating patients. Often doctors have reported that it would take a great deal of effort for them to discover what the prices of the medical services they rendered end up being for the patient's insurer and the patient themselves. That's one real aspect that I can speak to as a consumer of health policy research and reader of the general journalism coverage of the patient's experience here in the U.S. If you talk about my view as a researcher studying large datasets, like IBM market scam claims database, like the Medicare claims database, both of which are gigantic claims databases with unit prices for every claim that's paid covering many tens of millions enrollees and beneficiaries in the country from that

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perspective through which I've written many papers, some of which are cited in attachment B as a researcher as a matter of ascertainablity and discoverability while the prices of medical services there are not opaque. They're clearly in the claims. There's a common way of studying them and a common way of reporting them. The figure in my report captures 19 studies reviewed by Kaiser Family Foundation, two of which I authored or co-authored out of 19 and the other 17 being peer studies that do the same thing of studying claims data to report the unit prices. In all of these 19 papers, the prices are not opaque because we report that as researchers. So there's a description for you of information deserves some specificity and why in my role I can see it -- I can answer your question from a couple of different angles here.

Q. Have you ever testified under oath that there's abundant academic evidence that shows pricing information in the U.S. healthcare system is opaque?

A. Well, again, in the context of the patient's experience, as I just described in detail --

Q. I didn't ask you for an explanation. You offered that testimony.

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A. I think I understand your question fully, sir, and I'll give you the response it deserves. In my other testimony, such as the one you have in your hand that we discussed this morning for the Lab Corp. deposition, which you have the transcript, if I recall, there is -- I can't recall my exact words off the top of my head from several months ago, but it's plausible that I said something to the effect of from the patient's perspective or at least discussing in the context of the patient's perspective having received a surprise billing in those cases, that in general, from the patient's perspective, medical prices in the U.S. healthcare system can often seem opaque, but as you can see, it's important for me to distinguish that perspective from which I was offering that testimony. If indeed those words are what you're looking at in front of you are as different than the view I have as a research scientist studying large datasets and publishing large sample size studies about the prices of medical services.

Q. Is the testimony that you offer under oath truthful?

A. Absolutely truthful and with the nuance that's appropriate with the statement you're quoting

me on with regard to the patient's perspective.
Q. Did you review the deposition from -- the transcript from your prior deposition?
A. I believe I did.
Q. Did you reserve the right to read it and sign it?
A. I honestly can't recall months ago whether I signed the transcript after reading the transcript. I certainly recall reading the transcript.
Q. Did you make any changes to the transcript when you read it?
A. Nope, not that I recall. I did not make a change to that transcript.
Q. Do you agree that healthcare providers often lack pricing information on the clinical services that they provide?
A. That sounds very analogous to something I would have testified to in that case, and it's almost word-for-word what I told you a few moments ago about how from the patient's and physician's perspective, there's ample popular press evidence, as well as academic papers, that have described the difficulty of both patients and physicians figuring out the unit prices of the care that they've rendered

and received, and that is, as I've clearly delineated for you, a different way of looking at the opacity of the healthcare prices or the clarity of healthcare prices in the U.S. system relative to the researcher's view working through large datasets and reporting on these prices in peer-reviewed publications.
Q. And is it true that one of the realities of our healthcare system in the United States is that a charge for a procedure, such as a colonoscopy that's administered in New York City, can be different from what -- is charged for the same procedure in Charlotte, North Carolina?
MR. MIGLIACCIO: Objection. Incomplete hypothetical.
THE WITNESS: Sir, do you mean charge or price?

BY MR. TRISCHLER:
Q. You tell me.
A. With all due respect, you're asking the question. I just want to know the entity that you're asking about, and I've defined both in my report. Do you mean price differences across different geographies or do you mean charge differences across

different geographies?
Q. Well, with all due respect, I guess we'll try to get answers to both questions. Is it a reality of our healthcare system that the prices charged for a colonoscopy in New York City is different from the prices of what a patient is charged for a colonoscopy in Charlotte, North Carolina?
A. Okay, I've clarified -- let me restate. I have clearly discussed in my report how and for what reasons prices vary geographically in the U.S. healthcare system. I would refer you to, just as one example, paragraph 23, if you'd like to take a look at that. If not, that's okay. Where I state, now that I'm looking at that page:
"Commercial prices for a given service vary substantially by geography due to differences in provider market power relative to insurers," and the reason that we should emphasize or highlight a statement like that is that price variation in commercial health insurance, which I describe here, is different than price variation geographically in Medicare.
As I've stated in my report, in the Medicare program, prices are largely uniform across

the country because it's a single-payor federal program with one fee schedule that has some variations geographically based on costs of living adjustments and whether a provider is a medical education provider or not and various other small adjustments on the fees, but by and large, there is plenty of evidence, as well as freely accessible fee schedule online, that demonstrates to you the uniformity of Medicare prices across geographies in the U.S., but commercial prices differ geographically based on provider market power differences relative to the market power of insurers. That's prices. I'm sorry. That's prices. So now you can, if you would like, ask the analogous question about charges or ask a different question.
Q. Thanks. I appreciate you for permitting me to do that. So the cost of a colonoscopy in New York City then will also differ depending on whether that patient has private insurance or is receiving Medicare. Correct?
A. Again, I think by "cost" you mean "price," and I have established in my report very clearly why prices differ across payors. In fact, I've given you table three and table two to show you concrete examples of Medicare and commercial prices

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that provides concrete examples for your question.
Q. I'm just looking for an answer to my question.
A. Commercial prices --
Q. Are the prices for a colonoscopy performed in New York City differ for a patient, on average, who is a Medicare beneficiary or a patient who has private insurance, yes or no?
A. Commercial prices, as a general matter of medical services, differ from Medicare prices in the ways that I have clearly laid out in my report.
Q. And even among patients who have the same private insurance, as I understand it, the cost of a colonoscopy can differ if the patient is receiving services from an in-network provider or an out-of-network provider. Is that true?
A. I've also discussed in my report and devoted a whole section in explaining how and why prices differ in network settings and out-of-network settings.
Q. And in the context of private insurance, the price paid to a service provider is the subject of private negotiations between the insurer and the provider. True?
A. In most cases in the U.S. healthcare

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system, prices of medical services paid by commercial insurers to healthcare providers are determined through negotiations between commercial insurers and the healthcare providers.
Q. And you don't have any visibility as to the particularity of the negotiations between a hospital or physician's group and a lab provider and that insurer. Correct?
A. That's not entirely true. The outcome of the negotiation is reflected through the unit prices that we all study in these large datasets. We all, meaning the health policy, healthcare services, research community, the community in using use large datasets to study this question of the prices of medical services see in a common way the result of those negotiations because we see in the datasets the unit prices of medical services, as reflected in the papers that we discussed earlier that I have -- some of which I've written. It's reflected in the tables here that I've provided for you in the report. And even though we're not privy or present in the actual negotiation in a closed door room between health insurers and providers, the result of that negotiation is reflected through unit prices, which are on a claim by claim level present in these

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datasets.
Q. How much does United Healthcare pay physician's groups in Buffalo, New York for a colonoscopy?
A. I do not have that price off the top of my head, sitting here for you today, but --
Q. How much does CIGNA --
MR. MIGLIACCIO: Objection. Let him answer the question, please.
MR. TRISCHLER: He just did. He said he didn't have that information.
THE WITNESS: I added a short dependent clause to the end of my sentence, which was but I can tell you that it's a discoverable or knowable ascertainable fact.

BY MR. TRISCHLER:
Q. How much does Aetna pay a physician's group in Des Moines, Iowa for a colonoscopy?
A. Similarly, a knowable and discoverable, ascertainable fact and a number that I don't have off the top of my head, sitting here for you today.
Q. How much does Aetna pay a physician's group in Portland, Oregon for a colonoscopy?
A. You know, out of fairness for your

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question actually, I have to ask you, to which physician group, to which hospital? I recall that in my report, I detail how prices differ across providers based on relative market power, as well as across payors. If you're going to ask me a hypothetical question about a service, you've given me the insurer, but you haven't given me the provider. So in fairness, if you're giving me an insurer and a provider, that's what constructs a final price in the end, and those are knowable, discoverable, and ascertainable prices, but your question actually is more general than it should be.
Q. So the insurer -- so the same insurer, whether it be Aetna, United Healthcare, CIGNA, whatever we talk about, they may pay different physician's groups different amounts for service?
A. That's correct.
Q. And they might pay physicians in Buffalo different than they pay physicians in Portland, Oregon?
A. For the same CPT code, yes. However, in all of our studies, the prices of medical services, such as the combination of 19 studies in the Kaiser Family Foundation review, researchers and analysts and policy makers use common measure of central

tendency, like averages or mediums or market-level averages or market-level mediums, to abstract from the individual provider group or insurer differs in prices to get to a market average, and it is very common for researchers and policymakers, as well as I would -- I would offer you decision makers in the private sectors of our healthcare economy to use those averages and mediums to construct measures of estimated spending, to construct potential sizes of budgets because what they're doing is multiplying an average price or a medium price or a price of 25 percentile or a price at the 75th percentile. They're taking a group of data that has variation within it, coming up with a measure central tendency or a measure that reflects on the whole what prices are, multiplying that by the quantities that they're multiplying to a monitoring program, as we discussed earlier, to come up with spending. So the use of the variation cannot be divorced from the fact that there is variation across geographies. So as you ask me about variation across geographies, I need to and I will continue to remind you that the use of that data abstracts from that variation and follows a common methodology in how we apply prices.

Q. Medical prices vary across geography.

Right?

A. I had just read you a quote from my report that alines with that, yes.

Q. And medical costs varies across providers?

A. Hold on. Let me go back. I need to revise my previous answer. In Medicare, again, as I just discussed earlier, prices do not vary much, if at all, across geography. There are small variations across the country within Medicare.

Q. I assumed your answer referred to private insurance.

A. Well, my fault there, and perhaps we both could have been more specific. I did not specify that Medicare does not have much price variation across the country. Commercial insurance has more price variation across the country. So if you were implicitly asking me about commercial insurance, my answer is yes, commercial insurance prices differ across the country in exactly the ways I have written in my report.

Q. And those ways, for my benefit, they vary across geography, they vary across providers?

A. Right, and it is not --

Q. And they vary across site of care, which

is another one you mentioned?

A. Yes, as you highlighted earlier in that exhibit on the screen for all of us to see, my report talks about variations between payors or between insurers. It talks about variation between sites of care, and it talks about variation between in network versus out of network, and all of that you just restated. The conceptual point I want to drive home here is that as I said in paragraph 23, when prices vary by geography, they vary because of differences in provider market power relative to insurers. That is an important source or explanation for the variation that we need to keep in mind. They don't vary because patients are different. They don't vary because employers are different. They don't vary because one patient was -- has a certain clinical characteristic and another does not. They don't even vary because some patients have higher cost sharing and other patients have lower soft sharing. Remember, prices are unit prices. Cost sharing is the portion of unit prices paid by the patient out of pocket or asked of the patient out of pocket. So when we think of price variation on the commercial side, there is variation by geography, but the variation is explained by differences of relative

market power between insurers and providers, not because of the differences in land. It's not because Portland, Oregon sits somewhere else than Buffalo New York that price differs. It's because within those two different geographic locations, the relative market power between insurers and providers differ. That's what explains the difference across geography and prices.

Q. And you -- in your report, you use a reference, I think national averages, to highlight those price differences, some of the price differences for services between Medicare and private insurance. Correct?

A. No, not to highlight, but to abstract from. It's the opposite of highlighting. It's showing you a common methodology adopted by researchers and policymakers in a standard practice within both the academic profession and the policymaking community, as well as employers and insurers, by the way, that when we think about price variation in a large dataset or a large population, we extract away from the variation by using a measure of central tendency, such as averages or medians, and in addition, there are instances where a decisionmaker or a factfinder might want to use the

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60th as opposed to the median or the 40th percentile as opposed to the median. If there are good reasons for selecting a different percentile, it's up to a decisionmaker to do so, but the common methodology remains, which is despite variation, there are ways of abstracting from the variation, not highlighting the variation in order to use and apply medical prices to quantities of care in a common way.

Q. If you were to apply your common methodology to a class that may be certified, what average would you apply or is that something that you still have to determine?

A. No, sir, that -- I've used ample space in my report to show how that's done and provided those illustrations in the tables in my report to give you concrete examples of how those prices would be derived, and I think in both the texts and various footnotes, I added sufficient detail for the depth of our discussion to describe how that application of the common methodology could be carried out.

Q. What is the average price variance between -- that you are relying upon between Medicare and the private insurance?

A. I think we should go to the report to answer that question.

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Q. You can. I'm just asking my question. You can go wherever you want.

A. Okay, give me a second.

Q. As long as there's an answer in there somewhere.

A. So the first place we could go, sir, is figure one on page 13. In this figure, you see average Medicare prices compared to average commercial prices across the 19 studies using data from 2010 to 2017. All of these data produced by health economists and other peer experts in the field. Two of the 19 studies, as I noted earlier, are ones that I personally wrote or co-authored, and to the extent I know those two papers and I know the peer 17 papers in this review, these papers compare averages to averages. So that's a concrete illustration of how one would go from an average Medicare price to an average commercial price. So if we take the example on the right-hand side of that figure for physician services, that is largely an independent physician office setting, not an HOPD setting, because an HOPD setting is the data point to the left of that. If we look at that data point on the right side of the figure, 1.43 percent with 1.18 to 1.79, as shown in the figure, is the average ratio

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of commercial prices for physician services to Medicare prices for physician services. We can unpack that a number of ways, but that's the way to read this result. Analogously, if you go to the outpatient department setting, HOPD, as I described earlier, hospital outpatient services, on average, are priced at 2.64 in commercial health insurance the level that they are priced in Medicare. Again, comparing averages to averages. So that is a set of concrete examples of how you would derive or formulate a common methodology around measures of central tendency well accepted in the profession or industry for going from Medicare prices to commercial prices, and there are even more direct ways, as I noted earlier. One can go to large dataset and directly measure average commercial prices without using a conversion through this ratio like this figure. That I've done in the JAMA 2019 paper, the exhibit table there that I noted earlier. So let me stop here, but happy to answer more questions on this.

Q. So glad you decided to stop. The ratio you cited is 143 percent. Right? That's what you told me. The ratio of private insurance to Medicare for physician services.

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A. The ratio is 1.43.

Q. And that's based on a metaanalysis of sorts looking at varies studies done over time?

A. That's a correct characterization of this Kaiser Family Foundation publication.

Q. And some of those studies found the ratio to be larger than 1.43, and some of them found it to be greater. Right?

A. You said larger and greater.

Q. I'm sorry. Some of the studies that were relied upon in the metaanalysis found the ratio to be greater than 1.43, and sometimes to be smaller?

A. If you go to that report, which I linked to in my references list, there is, in fact, another figure that displays for you that information around 1.43. That's the measure of central tendency coming out of all this literature. So I would just draw an analogy for you here, sir, because I think what you're asking about here can be aided by an analogy that's not so germane to medical claims data. If one were to ask you what is the average price for a gallon of gasoline in the country, you would not be surprised if the evening news reported an average price. You also wouldn't be surprised if a gallon of gasoline costs a little bit different from one state

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to another or one county to another or in a place where there are more gas stations competing against each other for customers or in another place where gas stations have more market power because there's less competition. This is analogous to that. In the healthcare economy, just like the economy for a gallon of gasoline, there are price differences, and price variations, as I've explained in my report, by geography are explained by differences in market power, but what does one do when we think of a common methodology for drawing from that real world price variation to formulate a way of studying or analyzing or using the prices of medical services or the price of gallon of gasoline. For sure you're not suggesting here that because there's price variation across the country or across gas stations, we can't come up with any idea of what a common price or an average price is, and I'm using that illustration here analogously to show in medical care, it's the same exercise. This 1.43 is the national average of the ration of average commercial prices to average Medicare prices. I've gone into great detail to explain where Medicare prices come from, that's the denominator here, where commercial prices come from, that's the numerator here. All of that is in the

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report, but I think the analogy -- well, I hope the analogy helps.

Q. The ratio of 1.43, what physician services is that based on? Is it all physician services that are offered across the country or some segment of physician services?

A. Great question. In the studies that comprise this metaanalysis or review, there are differences in the datasets and the years of data that are used, and therefore, there are differences in the samples of medical services used to construct those studies. Off the top of my head here today, I cannot reconstruct for you from memory the differences in those samples, but suffice to say that these are not 19 identical studies in this review. Obviously, there will be some differences across studies.

Q. And the services that are part of this metaanalysis that arrived at the ratio of 1.43 are not the same -- are not based on the same six services that are the framework for what you described as a medical monitoring plan?

MR. MIGLIACCIO: Object to the extent it misstates testimony, but you can answer.

THE WITNESS: With a fair degree of

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certainty, I can report to you that at least some of the six illustrative services that I provided in my report also do exist in a number of these studies. A concrete example is my 2019 JAMA paper, which is part of these 19 studies reviewed here, has the price of an office visit. It has both Medicare and commercial and in and out of network, by the way, and it has the price of a number of other services that we could easily refer to. And because I've illustrated for you six common examples of services that are very common, like a urinalysis or an office visit, it would not be surprising to me at all. In fact, I would expect that these services appear in many of these 19 studies. I simply haven't performed the exercise of manually going through each of the 19 studies and comparing whether the same six illustrative examples also appears in each of those studies. That's something one could do, but I have not done that to date.

BY MR. TRISCHLER:

Q. And I wasn't even asking you -- that was not even my question. My question was not do these six services appear anywhere within any of the studies that comprise the metaanalysis. My question

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was: Has there ever been an analysis of just these six services that are the framework for your monitoring plan and tell us what the ratio, payment ratio, was from between Medicare and private insurance in 2018?

MR. MIGLIACCIO: Objection to the extent it misstates testimony. You can go on.

THE WITNESS: Thank you for that clarification. That actually makes me think about your question differently than the question I thought you had asked, so I appreciate that. One fact about medical pricing that is essential for answering your question here is that when a provider organization negotiates for a commercial price with an insurer, what they negotiate on is the relative value unit or RVU conversion factor, which is then uniformly applied to all services in the physician fee schedule. Therefore, in other words, provider organizations and commercial insurers do not negotiate one for one the price of service A, then service B, and service C, and so on. There are thousands of medical services. What they do, as I believe I explained in my report, is they take the underlying relative value units, the RVUs, of services as given from typically the Medicare

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program, and they largely negotiate on the RUV converse factor which then formulates the pricing contract between the private insurer and a private organization. That conversion factor is by definition a common methodology itself because then it's applied to not only these six services in my illustrative examples, but all the fee services in the fee schedule. So when you ask is there a study that only looks at those six services, with that essential fact I just described to you, you can now see whether a study analyzes the six services or 16 services in the fee schedule or 600 services of the fee schedule or 1,000 of the services in the fee schedule. Because that RUV conversion factor is common and uniformly applied to all the services in the fee schedule, the resulting ratio of the commercial to Medicare prices should be very similar. So even if there isn't a study that looks at these six services, a study that does so should not, in principle, arrive at a very different ratio of commercial to Medicare prices that a study that looks at all of the services.

Q. I appreciate your speculation that you wouldn't expect it to be different. Can I get a simple answer to a simple question?

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Has there been a study looking at the foundational services that you mention in your report and calculating a ratio between Medicare payments and private insurance payments? Has it been done, yes or no?

MR. MIGLIACCIO: Objection to the colloquy and also objection to the extent it misstates his testimony.

THE WITNESS: Because you're trying to re-ask your question, I'm going to rely on the prior iteration of your question, which specified that you wanted to know about a study that only looked at these six services and nothing else, okay, because you did not specify that in this latter iteration of the question. As I've noted before, many of these 19 studies and potentially others outside of the metaanalysis have examined the six services or a subset of these six services. And although I don't know of a study that only looked at these six services and nothing else, the result from an analysis of these six services versus an analysis of 16 or 600 or 1,000 services ought to arrive at a similar ratio of commercial to Medicare prices because of the essential fact of the RUV conversion factor being commonly applied the fee schedule, which

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I just described to you.

Q. Do Medicaid reimbursement rates differ from state to state?

A. There is empirical evidence that Medicaid prices differ state to state because we have 50 states and 50 different Medicaid programs. They are administered by state governments with financing by the federal government. The Kaiser Family Foundation Medicaid price index or conversion -- I'm not getting the exact name of that source right, but it's in a footnote in my report. I'm happy to find it. That shows you literally in a table format with 50 rows the average Medicare -- sorry, the average Medicaid prices across the 50 states, and you can compare them in apples to apples version to each other.

Q. Is the ratio between private insurance and Medicaid, taking a 50 state average, a greater or less than 1.43?

A. If you're asking me to give you a calculation of average commercial prices versus average Medicaid prices, right, I think I heard that correctly, average commercial prices divided by average Medicaid prices should yield a higher ratio than higher average commercial prices divided by

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average Medicare prices. So the average ratio on this figure of average commercial prices divided by average Medicare prices is 1.43 for physician services in the independent office setting. Therefore, if you divide the average commercial prices by average Medicaid prices, which are lower than the average Medicare prices, then the average ought to be higher than 1.43.

Q. Do you know what that ratio is?

A. Off the top of my head, I could give you an informed hypothesis, but I don't know the exact ratio without having done that calculation in recent memory.

Q. That's fine. If you don't know, you don't know.

A. It's not exactly that I don't know, sir. I have a general idea. I've even shown you in a footnote here. I think 0.72 is the ratio of average -- just give me one second. I want to get this correct because your characterization that I don't know is simply not accurate here, I apologize.

So in footnote to table six on page 24, I write in the fourth line of that footnote:

"Medicaid prices are estimated by using the national average Medicaid to Medicare physician

fee ratio of 0.72."

So there you've got it. A 0.72 is the national average Medicaid to Medicare physician fee ratio. So arithmetically, you can use that in combination with 1.43 to derive what the ratio of what 1.43 would be for commercial versus Medicaid. I'm happy to do the math if you want to give me a few minutes, but this is the ingredient you would need to get that math done.

Q. I just asked you if you had it or not. If you don't have it, that's fine.

A. Out of respect, sir, then you qualify or characterize my answer as if I don't know, then I don't know. Look, I've shown you the formula and discussed with you the ingredients you need to calculate that. I've simply not performed that calculation. But I would argue that that's different than having no idea.

Q. So you're not supposed to argue, sir, respectfully. You're supposed to answer the questions.

A. With respect, by "argument," I don't mean temper or tone, but rather as respectful pushback of your characterization.

Q. There's not supposed to be any argument,

respectful or otherwise. Just supposed to be answers to questions, sir. So let me try something else.

The ratio of 1.43 that you cite, when was that ratio published?

A. I believe April 15, 2020, was the publication of that Kaiser Family Foundation report. The citation is right here in my report. You can go online and verify that.

Q. Was it based on pricing for commercial insurance and Medicare reimbursements in 2020, 2019? What period of time?

A. Again, as noted in figure one, which we just reviewed together or at least I reviewed on my screen, I'm not sure if you saw it in conjunction, in the box right there, it clearly states using data from 2010 through 2017.

Q. Has there been any ratio published for data from 2018 to 2021?

A. Off the top of my head, I don't have a citation for you. I would not be surprised if this large academic community continues to work on this issue of price range rations and further work has been published. I have not had a chance to look into that. With that all said, price ratios across years, even across these years from 2010 to 2017, which is a

longer span, in fact, twice as long as the one that you just proposed from 2018 to 2021 do not shift around all that much. In other words, the 1.43 you get from 2010 to 2017 data, you can generally expect the ratio from other years to fall somewhere in that vicinity as well.

Q. I appreciate that speculation, but I'm just asking a simple question. Have you seen any studies establishing a payment ratio between Medicare and commercial insurance covering time period 2018 to 2021?

MR. MIGLIACCIO: Object to the colloquy. Asked and answered.

THE WITNESS: So beyond these 19 studies, which formulates the evidence based to date, I don't have at the moment an additional citation to provide you from a more recent year of data.

BY MR. TRISCHLER:

Q. And none of those 19 studies from the metaanalysis include the pricing data from 2018 to 2021; do they?

A. To my knowledge, they used data from 2010 to 2017. So I believe 2017 was the last year.

Q. And do you agree that future prices of

medical services in the United States remain uncertain given the opaqueness of the U.S. healthcare system?

A. No, I do not agree with that, sir.

Q. Have you ever testified that future prices remain uncertain given the opaqueness of the U.S. healthcare system?

A. Again, from the patient's perspective and the individual frontline clinician's perspective, I've described for you twice now why both stories in the Lay Press and academic articles have characterized the patient's experience in finding out the prices of the care they're receiving as challenging and the prices as opaque to patients. Those prices have been opaque to patients. They are opaque to patients currently, and therefore, it would not be surprising if they're opaque to patients in the future. From that perspective, I would not be surprises if I offered testimony in that line of reasoning in the prior transcript that you have in your hand. Similarly, frontline clinicians themselves have also found it challenging in various news articles and academic studies to discern the unit prices of the care they're actually providing because as we discussed, negotiations over prices

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take place at the organizational level, not doc by doc on the front lines relative to insurers. Opaqueness today for frontline doctors and for patients leads me to believe that unless something fundamentally changes about the way prices are reviewed by the U.S. healthcare system large, then we can expect qualitatively the same kind of opaqueness going forward, but that is different from the perspective of empirical researchers like myself and the authors of the other 17 studies in this metaanalysis who examine large datasets comprising millions -- tens of millions of enrollees both Medicare and commercial where that the unit prices are clear. I mean, they are printed per claim and analyzed with statistical software, with statistical precision, and methods. So opaqueness I would not use to characterize that lens of analyzing prices.

Q. Well, none of those 18 -- is it 18 or 19 studies?

A. 19 studies in this metaanalysis that we're talking about.

Q. So none of those 19 studies in the metaanalysis look at future healthcare costs. True?

A. Well, I submit to you as a matter of general principle that in empirical studies of data

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that exist today of past events, data from the future are not part of empirical studies.

Q. Okay. Another way to answer that question is yes, you're right. So those studies do not look at future data or project future ratios?

A. But they tell us something about how --

Q. I didn't ask you that. You've got to answer my question.

A. But it's a misleading question, sir.

Q. You haven't even heard it yet.

MR. MIGLIACCIO: Let him ask his question and then you can give your response to it.

MR. TRISCHLER: Then you can argue all you want once I get to ask it.

MR. MIGLIACCIO: Object to the colloquy. Ask your question, counsel.

BY MR. TRISCHLER:

Q. Do the 19 studies that comprise the metaanalysis project future ratios of healthcare costs between commercial insurance or future healthcare prices between commercial insurance and Medicare?

A. These 19 studies using 2010 to 2017 data teach us something valuable about how a health policy

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or healthcare services analyst would think about future prices in our healthcare system, specifically the ratios of commercial versus Medicare prices. Of course no one can exactly predict the future. However, if you see empirically, stability of price ratios across years, you would logically or one reasonable-minded person would logically infer that unless a big intervention happened in healthcare pricing or a big federal policy that one did not anticipate came down the road that stability of ratios of prices across years would lead one to believe that the ratios would likely continue to be stable in the absence of a large intervention or policy. So, of course, no study using prior data predicts the future, although some studies do simulation methods to make predictions, these 19 studies do that, but of course we learn something about how we think critically about the future based on evidence from the past, and that is exactly an analogy we can draw from these 19 studies as you would draw from many other domains of science. We learn from data from the past to inform how we think about data from the future. So the very fact that future data are not in these studies because of course the future hasn't occurred yet, doesn't mean

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that the studies tell us nothing about how we think through prices in the future. That's the only point that I'm trying to emphasize here. That's why frankly I found your previous question misleading because it didn't give me the room to offer this nuance.

Q. Have you had enough room to offer the nuance now or do you need more?

A. No, sir, I'm satisfied with the answer I just provided you.

Q. Good. Good. Have you given any thought of how long this yet-to-be certified medical monitoring program would remain in place?

A. Again, that is a dimension of quantities, what services are in the monitoring program, who is in the monitoring program, for how long one is in the monitoring program.

Q. So you haven't given it any thought -- you faded out, so I didn't hear your answer.

A. I'm sorry if I faded out. What I was saying was the duration of monitoring program analogous to the services within a monitoring program and who is in a monitoring program are all aspects of quantities, and because prices times quantities equals spending and because my report focuses on

prices, not quantities, these substantive questions about quantities are outside the scope of my report, which we've clearly established repeatedly earlier.

Q. So as you sit here today, you don't know whether the program that you are supposed to monetize will provide healthcare services five years into the future, ten years into the future, 20 years into the future, or 50 years into the future. Right?

A. By the very definition that a monitoring program has not been finalized and certified, I do not know what's in the final certified monitoring program. Nevertheless, the common methodology for applying prices can be used for any monitoring program that would be certified, and again, that was around quantities or what's in the monitoring program was outside the scope of what I was retained to opine on.

Q. And your methodology then would be, among other things, to look at average prices for physician services from 2010 to 2017 to predict what prices would be for those services in 2040?

A. I disagree with your summary there because there's nothing in my report that restricts the common methodology to just those eight years of data. As time passes and new data becomes available,

you can easily extend this common methodology to include newer data from 2018 and onwards, for example, and it does not preclude the -- the use of, as I noted before, the 40th percentile or the 60th percentile or the 75th percentile. A judge, jury, or decisionmaker, or factfinder could decide to use a different measure of central tendency within the distribution. An average is but one option. It's not the only option.

MR. TRISCHLER: I do not have any further questions for you at this time. Some of the other counsel may. Thank you for your time.

THE WITNESS: Thank you, sir.

THE VIDEOGRAPHER: The time is 4:59. This ends media unit No. 5. We're going off the record.

(Whereupon, a brief recess was taken off the record.)

THE VIDEOGRAPHER: The time is 5:08. This begins media unit No. 6. We're back on the record.

CROSS-EXAMINATION

BY MR. OSTFELD:

Q. All right. Hi, Dr. Song. It's nice to meet you. My name is Greg Ostfeld. I represent Teva Pharmaceuticals U.S.A., Inc. and several related entities in this case. Okay?

A. Hi, Greg. It's nice to meet you as well.

Q. You've noted a few times today that no class has yet been certified in this case, and that's certainly true. You were provided with a definition of the proposed medical monitoring class by plaintiff's counsel. Correct?

A. Proposed to the extent I recollect the documents I read in the case, yes.

Q. And that's the definition that you reference on page 4 of your report and what you and Mr. Trischler discussed earlier. Right?

A. Yes.

Q. You also discussed a phrase "patient population" a number of times with Mr. Trischler. Do you remember those discussions?

A. Not the exact context of his questions, but I do recall using the phrase "patient population."

Q. And that phrase also appears on page 25 of your report. Probably other places as well, but I'm thinking of the usage on page 25 that you went over with Mr. Trischler.

A. Do you mind if I take a second just to find that?

Q. Of course.

A. In line four of paragraph 29, I wrote "patient population." I used that phrase there.

Q. And in fact, a patient population is a relatively important component of your model because once you've ascertained the prices of each of the procedures included in the medical monitoring model, you then have to determine the size and composition of the patient population to come up with the quantity size part of your model. Correct?

A. Not exactly like you phrased it because I'm taking the dimensions of quantity as given in the context of this report. So I am not making, nor was I asked to make a determination about the elements of quantity, such as the services in the monitoring program, who is in the monitoring program, the duration of the monitoring program. Those are elements I was not asked to opine on, and to my understanding, are being worked on by other experts

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in the case, and my work was around the common methodology of applying my knowledge about pricing -- in an approach towards of whatever services end up being in a potential medical monitoring program that gets certified.

Q. I want to make sure I understand your answer correctly. So as I understand the testimony that you've given several times today, you haven't applied your model to a given class, a given set of services, or a given patient population. You've demonstrated how your model would be applied. Is that fair?

A. Because of the absence of a final certified class of patients or a certified or final medical monitoring program, yes, my report provides illustrative examples of how a common methodology for pricing would be applied.

Q. Since your model in simple terms is price times quantity, the quantity side of that formula is essentially the patient population and the procedures that are performed on the patient population once it is ascertained?

A. It includes -- I would agree that it includes those two elements.

Q. And I guess another way of putting it

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might be the price is the price of each of the procedures included in the medical monitoring program. The quantity is the quantity of those procedures performed on the patient population included in the medical monitoring program. Is that accurate?

A. That is a fair characterization of price times quantity in this context.

Q. So if the court were to certify the class that you define on page 4 of your report, would the members of that class then constitute the patient population referenced on page 25 of your report for purposes of ultimately applying this model?

MR. MIGLIACCIO: I'll object to the extent that it calls for a legal conclusion, but you can answer that.

THE WITNESS: Yeah, to be concrete, in line two of paragraph 39, when I say the size and composition of the patient population undergoing monitoring, by "patient population," there I do mean a final certified set of class members.

BY MR. OSTFELD:

Q. Okay. I think I like the way you said it even better. If there's a final certified class,

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the members of that final certified class would constitute the patient population?

A. As I'm using it in paragraph 39, lines two and four here, yes.

Q. Now, in this instance, the proposed class definition that you were given consists of all persons who consume the defendants Valsartan-containing drugs containing NDMA or NDEA and who accumulated sufficient quantities of lifetime cumulative exposure to require medical monitoring given the increased risk of cellular and genetic injury leading to an increased risk of cancer. Right?

A. I believe you just read from paragraph 7 of my report. Is that correct?

Q. Probably because I tried to cut and paste from it earlier.

A. To the extent that you read word for word in paragraph 7, I certainly stand by what I wrote.

Q. If that were the class and the court were to ultimately certified to estimate the size and composition of the patient population, we would first have to determine who the members of that class are. Right?

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A. Yes, that seems synonymous.

Q. So that means that you have to identify all of the persons who consume the defendants Valsartan-containing drugs containing NDMA or NDEA and who accumulated sufficient quantities of lifetime cumulative exposure to require medical monitoring given the increased risk of cellular and genetic injury leading to an increased risk of cancer. Right?

A. Well, you're leading me down a hypothetical here because the class has not been certified. If in your question you're asking me to assume that a final certified class is certified based on the exact words of the -- of the summary of proposed class definition here, well, then my summary of the proposed class definition here would, therefore, be the definition of the class. I think you're just equating two things there forward and now backwards.

Q. You understand that you're describing this as a hypothetical, but you understand that this is the hypothetical that the plaintiffs are attempting to make into a reality in the conclusion of this case. Right?

MR. MIGLIACCIO: Objection to the form

of that question.

THE WITNESS: I appreciate your question, sir. Not as an attorney in this case, I feel it's not my place to say what the plaintiffs are trying to do. I am only discussing and offering my expertise on what I've done in this report. I think out of respect for the plaintiffs and plaintiffs' counsel, I'm not going to purport to characterize part or everything that they're doing in this case. That's not for me to do.

BY MR. OSTFELD:

Q. Sure. You understand that your expertise is not being applied in a purely hypothetical context. It being applied to litigation. Right?

A. Well, my expertise in this case is being applied to the pricing of medical services, which, in my view, is germane to the substance of the case here, but it's a fairly narrow task that I was retained to conduct, and there are lots of important questions around class membership and definition in the monitoring program components itself that we talked about at length today, which frankly is outside the scope of this report again.

Q. That's sort of what I'm getting at, is to apply what you have brought to this case. Ultimately, somebody, and it may not be you, but someone is going to have to determine who is in the patient population, somebody is going to have to determine what tests are going to be administered to the members of the patient population, and then your model can be applied to estimate the price of doing so. Right?

MR. MIGLIACCIO: I'll object to the extent it calls for a legal conclusion, but you can answer.

THE WITNESS: Answering not as an attorney myself, that characterization of a future series of events makes sense to me logically as a health economist offering an opinion here.

BY MR. OSTFELD:

Q. Okay. Whether it's your exact wording or not, you understand that the proposed class definition includes a determination of persons who have consumed enough Valsartan-containing NDMA or NDEA to cross a lifetime cumulative exposure that puts them at a greater increased risk of cancer?

MR. MIGLIACCIO: Same objection. You can answer.

THE WITNESS: To my general knowledge of the facts of the case based on what I've read and based on my discussions with your colleague earlier today, yes, my understanding is that there's a point system that helps define a threshold of cumulative exposure, and that point system and threshold helped define then the proposed class members. That is my general understanding of that area of the case.

BY MR. OSTFELD:

Q. So if a class were certified that meets those characteristics, then to know the size and composition of the class, we have to identify the persons who have crossed those lifetime cumulative exposure thresholds. Right?

MR. MIGLIACCIO: Same objection to the extent it calls for a legal conclusion. You may answer.

THE WITNESS: I think conceptually you're asking something that's very simple here. It's so simple that I don't know if it's a trick question or not. If the definition of membership into a class is X, once a person satisfies X, then I would expect that person is part of the class.

BY MR. OSTFELD:

Q. It's not a trick question. I don't ask trick questions. I ask simple questions, at least I try to, and if I get them wrong, I try to ask even simpler questions.

I think you put it very well. To -- if a class is certified, we have to determine who the people are who meet the X criterion that qualifies them for membership in the class. Right?

MR. MIGLIACCIO: Same objection. You can answer.

THE WITNESS: That seems logical to me.

BY MR. OSTFELD:

Q. And once we know who the people are that meet the X criterion, then we know the size and composition of the class and can apply your model?

A. Well, to be precise -- excuse me one second.

THE VIDEOGRAPHER: The time is 5:21. We're going off the record.

(Whereupon, a brief recess was taken off the record.)

THE VIDEOGRAPHER: The time is 5:22. We're back on the record.

THE WITNESS: To be precise, based on your question, if you determine the members in a class, it seems to me, even though this was not a subject that I was asked to opine on, but it's a matter of logic, it seems to me that you've defined the size of the class, but the composition of the class would not yet be defined simply by knowing the members of the class.

BY MR. OSTFELD:

Q. That's an excellent point. Let's talk about that a little bit. Now, I think you said it was not part of your assignment to actually ascertain who the members of the proposed class are. Correct?

A. Correct.

Q. So you were given a definition, but you then did not then venture out and try to ascertain who in the U.S. population belongs in that proposed class definition. Correct?

A. Correct.

Q. Okay. So let's assume somebody else goes out and performs that exercise and they have now

determined who in the U.S. population is a member of the hypothetical certified class. Once we have that, how do we then determine the composition of the class?

MR. MIGLIACCIO: Object to the extent that it's a hypothetical -- an incomplete hypothetical at this point.

THE WITNESS: The methodology of how in your question is not something that I have devoted time thinking through and formulating a response to, and again, it was not part of the scope of the work to date that I have a been retained to do in this case, but based on what I've written in my report, aspects, such as insurer mix, are ascertainable by methods plausibly as simple as asking the class members or potentially could be information be volunteered by the class members. So there may be elements of that methodology for the how in your question that I'm not thinking of at the moment because I have not yet devoted time to that question, but I think as a matter of straightforward logic, if there are aspects of the population that are knowable and ascertainable, there are likely methods to discover or ascertain those attributes.

BY MR. OSTFELD:

Q. Okay. So that's fair. Among the factors that you identified that might be relevant to the composition of the class are issues, like insurance mix and age. Right -- or actually, I think you said life expectancy, not age. Insurance mix and life expectancy are both things you would want to know about the class?

A. I just want to go to my report where I talk about that.

Q. Okay.

A. So in paragraph 39 -- we've talked about insurers and insurer mix. So to take the second part of your question first, in paragraph 39 starting in line four, I state that projecting future healthcare use requires assumptions about life expectancy and the development of medical conditions. Those assumptions I have not been asked to formulate or state or propose or make in any way.

I, as a matter of conceptual piece to this common methodology, stating that those elements would be needed in the finalization or certification of a monitoring program and would be helpful for determining quantities. Again, quantities are what services are in the program, who is in the program,

for how long in the program. We talked about this earlier today in some depth, and this section of my report is a reaffirmation of a need of those elements to carry out an estimation of healthcare spending.

Q. So to apply your report to determine quantities, one would want to determine circumstances, such as insurance mix, life expectancy, and development of medical conditions, that may render the monitoring program less appropriate clinically. Right?

MR. MIGLIACCIO: Objection. Misstates.

THE WITNESS: Clinical appropriateness is a sort of sophisticated entity. I just published an original research article about clinical appropriateness. I think the way you're characterizing that here I would in some ways agree with, but I think it's easier and more applicable to this case to say that life expectancy and the development of medical conditions may inform a factfinder or a decisionmaker at the end of the day regarding what medical services ought to belong in a monitoring program.

BY MR. OSTFELD:

Q. And Dr. Song, to be clear, I wasn't

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trying to characterize. I thought I was reading from your report. I believe what your report says is beyond insurance mix, it says in addition -- let me start with line two of your report. It states:

"This involves," this being estimating the size and composition of the patient population. "This includes determining the insurer mix, site of care composition, and network status of the providers for the patient population. In addition, projecting future healthcare use requires assumptions about life expectancy and the development of medical conditions (e.g., cancer and other acute and chronic diseases) that may render the monitoring program less appropriate clinically."

Those are your words. Right?

A. Yes, thank you for reminding me. I had not recalled a moment ago that I used the phrase "clinical appropriateness" or "appropriate clinically" in the context of this part of the paragraph. Yes, I think that characterization is fair. Obviously, I stand by what I wrote in this report.

Q. Okay. So once we know who is in our class, these are the kinds of determinations that we need to make about the class members in order to

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determine quantity and apply your model. Right?

A. I think the factfinder through the process of certification would likely take these considerations into account in determining the final monitoring program.

Q. Okay, and I think one of the things you said is at this point you have not yet been engaged to undertake the issue of how to go about determining those, but one way might be to ask the class members. Right?

A. That is a fair characterization of our earlier discussion, yes.

Q. So you go to each class member and you basically say, "Who provides your medical coverage, if anyone," and based on your responses, you know how many Medicaid, you know how many Medicare, you know how many insured, and you know how many uninsured you have in the class?

A. That appears to me to be a common methodology for discerning insurer mix.

Q. And that assumes 100 percent response rate or could we extrapolate from a more limited response rate?

A. For the purposes of our discussion, I think it's fair to assume that if members participate

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within a certified class in a class action case, that there is likelihood -- obviously, this is an empirical question, but likelihood that they would offer some aspects of useful information like that. It is a hypothetical because you're asking about response rates in the future for a not yet determined class, but I'm giving you an informed guess, sort of a hypothesis about how I think a response rate would -- would go.

Q. Okay. How about the issues of life expectancy and medical conditions, how would we go about ascertaining that from the class members?

A. Similarly, you could ask them about medical care that they've received before in the exercise that I was led through by your colleague counsel in earlier hours. He readily demonstrated that you all and I imagine the plaintiffs' counsel have a great deal of information about the medical history of each of the plaintiffs, and again, this is not something I was asked to opine specifically about, but the methodology for determining these assumptions or these elements that are helpful for the calculation of healthcare spending, but as a matter of logic, I would imagine that if you could ascertain those aspects now, you could similarly

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ascertain those aspects of a person's medical history and risk factors similarly for a class.

Q. So in the same manner that we have gathered medical history information about the named plaintiffs, we can go gather that information about the class members and apply it to determine life expectancy and medical conditions?

MR. MIGLIACCIO: Objection. It assumes facts not in evidence, and it's an incomplete hypothetical.

THE WITNESS: I would agree with you can, but I would not restrict that general method we just walked through as the only potential methodology. For example, if you have a population that is large enough to be representative, you may be able to use a sampling procedure or what is common knowledge about the prevalence of certain diseases in the population to make an informed estimation or calculation of risks going forward. That is an alternative methodology to the one that you've used to gather information to date from the plaintiffs.

BY MR. OSTFELD:

Q. Okay.

A. I'm sorry, I was just going to add it's

one alternative among potentially others.
Q. Just so I can put some parameters around that, how large of a population would we need and how large of a sample size would we need to apply that alternative methodology?
MR. MIGLIACCIO: Objection. It's an incomplete hypothetical. Vague.
THE WITNESS: Thanks for these questions. From a research perspective, from a social science and empirical data perspective, it depends on the outcomes or clinical events you're measuring. This is not something that I've yet to spend time doing, so at the moment sitting here, I don't have the work done to answer that question, and it was not part of what I was retained to opine on to date, but in a general sense, it depends what you're measuring.

BY MR. OSTFELD:
Q. Okay. I want to ask you a few more questions on the phrase "medical conditions that may render the monitoring program less appropriate clinically." You know, I see that you've listed cancer and other acute and chronic diseases as examples of that. Help me understand, why would a

medical condition render a monitoring program less appropriate clinically?
MR. MIGLIACCIO: Objection to the form of the question. You can answer.
THE WITNESS: Let me provide you my response in two parts. First, the very definition of monitoring conveys that one is on the lookout or looking for an event that has not yet occurred. So if a cancer that you're monitoring for has already occurred previously in a person's life, that may change how we feel or how a decisionmaker or factfinder may feel about the appropriateness of the monitoring service.
The second part of my answer is that, to my understanding in this case, the proposed class for medical monitoring includes individuals who have not yet developed cancers that you would be monitoring for, and that, again, I'm not an attorney in this case, so please excuse me if I'm off a little bit on the details, but that there are other aspects of this case and other classes of this case that pertain to other individuals that fall outside of this proposed class for medical monitoring.

BY MR. OSTFELD:

Q. Does your -- strike that.
Is there a methodology or a method that can be applied to account for the exclusion of class members for whom medical monitoring becomes clinically inappropriate?
MR. MIGLIACCIO: Object to the extent it assumes facts not in evidence.
THE WITNESS: Again, that common methodology was not part of what I was retained to work on or opine on thus far in this case, and I would refer you to the oncologist expert with regard to that specific question.

BY MR. OSTFELD:
Q. All right, your model makes no assumptions about who the final decisionmaker is in terms of what medical monitoring is appropriate for members of the proposed class. Right?
A. Correct, it makes no such assumption about who that decisionmaker is.
Q. I think you described earlier that the model is agnostic to that?
A. I agree with that.
Q. So it could be a court, it could be a jury, it could be some board or standard setting

organization, or it could be individual doctors. Regardless, that's not something that your model requires be one thing versus another?
MR. MIGLIACCIO: Objection. Assumes facts not in evidence.
THE WITNESS: In the way that you listed those options, those all seem to be reasonable candidates for what a decisionmaker or a decisionmaking body could be, and I'm particularly grateful that you mentioned individual physicians as part of those options because with your colleague earlier, I had discussed at some length about the derivation of professional society guidelines for cancer screening in the United States. I had noted that those cancer guidelines are constructed by large bodies of scientists and physicians and other cancer experts. What I didn't get a chance to emphasize earlier on is that those large national professional society guidelines have characteristics that are different from a potential medical monitoring program, and it's plausible that an individual physician, as you just said, could be a decisionmaker or part of a potential decisionmaking body for a medical monitoring program that uses and builds on the evidence base of national professional society

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guidelines. So thank you for bringing me back to that point as well.

BY MR. OSTFELD:

Q. Sure, and I have a follow-up question on that. So to the extent we're trying to apply your model in a forward looking way, you know, we're trying to design a medical monitoring program that's going to be applied for, let's say, the next ten years, is there a method or a methodology to account for that individual physician component of this or an individual physician might decide with their patients that this type of monitoring is not right for their patient under their patient's circumstances?

MR. MIGLIACCIO: Objection. It's an incomplete hypothetical and assumes facts not in evidence.

THE WITNESS: As best as I understand your question, the common methodology that I proposed in this report respects the potential role of patient and provider preferences, and I've said this in a couple of different ways to your previous colleague as well. I was asked earlier, is there a role for a physician -- physicians and patients. Perhaps I was asked about both. Similar to my answer for you here,

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the concept that I'm trying to convey is that this common methodology about applying prices of services to a potential medical monitoring program does not restrict, does not prohibit, certainly leaves room for physicians and patients to have a discussion about their clinical care as is routine in our healthcare system.

BY MR. OSTFELD:

Q. Maybe I can put it in more concrete terms because we're talking about the same thing, but in slightly different ways. Maybe we can go back a page in your report to table six. This is your illustrative list of procedures.

A. I'm there at table six.

Q. So each of these six illustrative procedures has a CPT code associated with it. Right?

A. That's correct.

Q. For example, for urinalysis, the CPT code is 81001. Right?

A. This example I've selected in this table, yes, that's the CPT code.

Q. Okay. Is that the only CPT code associated with urinalysis?

A. No, it's not because urinalysis

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comprises a number of CPT codes. I think roughly about ten or 11 from which I have selected one of the most common ones, if not the most common one, and it is also worth noting that across those different urinalysis CPT codes, prices are generally similar, generally similar.

Q. Now, generally as a qualifier, when you say, "generally similar," is there a variance between them?

A. Prices can differ across CPT codes, yes.

Q. Can you estimate the general percentage of variations among different prices for different urinalysis CPT codes?

A. Do you mean within one payor or across payors or one insurer or across insurers?

Q. Let's go with something a little more fixed, like the Medicare price, amongst Medicare prices.

A. As best as I can recall because I've done prior research on this for a paper that I believe I cited in my report, off the top of my head in my analysis for that paper, Medicare prices for urinalysis CPT codes are in the order of, generally speaking, a few dollars. So this example of $3.17 is certainly the ballpark of what I recollect. The

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percentage variation across Medicare prices for those codes is difficult for me to quantify off the top of my head, but to try to be helpful, I can try give you an educated guess that it is small. It is going to be a few percentage points or tens of percentage points, but you will generally not see one urinalysis code priced at $100 or another one, a neighboring CPT code priced at $3. Hopefully, that helps gives you a sense.

Q. It does, and earlier you mentioned private insurance, so let's move over to the commercial price column. How does the variance differ from the commercial price versus Medicare price for the different urinalysis codes?

A. Well, conveniently --

Q. Let's go to a different procedure. Let's go to something different like upper endoscopy. So for upper endoscopy, that's a more expensive and more complicated procedure. Right?

A. You mean more expensive as in higher priced in commercial insurance relative to in Medicare.

Q. Even versus urinalysis, upper endoscopy is more complex and more expensive than urinalysis. Correct?

A. Yes, sir. My table supports that.
Q. And unlike a pure lab test for upper endoscopy, the price is not identical for Medicare and commercial. Correct?
A. Correct.
Q. So this might be a better example. So within the Medicare price range, let me ask you this: Is there more than CPT code for upper endoscopy?
A. Yes, I believe there is, and I'm not able to recall off the top of my head right now exactly how many codes.
Q. Are you able to recall or estimate the percentage variance for the Medicare prices for the different endoscopy codes?
A. Off the top of my head, I am less able to estimate that variation across codes that I am across the variation of urinalysis codes because upper endoscopy codes can include things like additional elements of the service -- I'm having trouble recalling from the physician fee schedule, which has thousands of physician services. It's fair to say that it's difficult for me at this moment to recall that variation.
Q. What about for commercial prices, would there be more or less variation for the commercial

prices of an upper endoscopy versus Medicare?
A. Well, that depends on where you look, sir. As previously discussed with your colleague, commercial prices vary due to differences in the market power relative to another geography. So it is plausible that you can find less variation among commercial prices and more variation among commercial prices based on where you look. Without going through the more granular exercise with you of asking you to be more specific about which area you're thinking about or what type of market power variation you're thinking about, I would just offer as a general comment from the research evidence base that Medicare prices are, in general, more uniform both across geography and across the codes, but I say the second part with some qualification without recalling the exact prices off the top of my head. And relative to that Medicare benchmark, commercial insurance prices, in general, do exhibit more variation because commercial insurers differ in their market power and providers whom they negotiate with differ in their market power across the country.
Q. And is there more variation between the codes as well on the commercial side?
A. There could be, and it's certainly

something that's ascertainable and able to be examined. Off the top of my head, I'm not able to give you a general conclusion about that, about upper endoscopy.
Q. That's sort of the scenic route to get to of what I wanted to talk about in terms of individual doctors and individual providers. You've used the word "ascertainable" a couple of times, so I want to understand what you mean by that. When you say that the price variance is ascertainable, are you saying that if you know who the providers are that are going to be providing the screening services and what services they're going to provide, then you can ascertain the prices they're going to charge?
A. That's certainly one feasible route, but it's not the only methodological route. As I noted earlier, from these large database, and I think I stated in my report, but I will just give this de novo here. In large datasets, like the MarketScan database, the Fair Health database, the Blue Health Intelligence database, the IQVIA database, and the HCCI database, which are examples of large databases of administrative claims data in the U.S., you can discern with common statistical methods and with a fair amount of certainty the average or median or at

least the range within a reasonable amount of prices for a particular service in a particular geography. Now, it may not match cent for cent to the negotiated price for a particular physician in a particular hospital or facility, but generally speaking, these measures of central tendency, especially within a region, such as an average or median of X percentile, should get you fairly close to what the market average for a price is, and so that would be a large database methodology that would serve as an alternative to the more specific ask each provider methodology that your question referred to.
Q. To apply the measures of central tendency, do you need to know the specific CPT codes or is it enough just know the name of the procedure being administered?
A. Either could work. That's a design decision. That's an empirical design decision, which I'm happy to discuss here, but would require some more thought to formulate a more thorough answer. In some types of services, all of the CPT codes within that shall we call it that category of service are rather similar. So an example here would be there are roughly ten or 11 codes for urinalysis in the CPT fee schedule, and although they may have some nuanced

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differences between them, many of them at the end of the day will give you basic information about cell counts and bacteria counts, and you can run the urine tests that you need off of them, whereas in other services, CPT codes have larger differences within a general category or type of service. So the design decision is you can either select the most common code, as I've done here using the illustrative examples, or you can determine that for this type of service, there are a number of codes here. They all generally would supply you the clinical data you need for monitoring or making a clinical decision, and therefore, for this particular example in this hypothetical that I'm raising for you, you may put all those codes together as a design decision. The common methodology can be applied either way, but it's an empirical sort of study design decision about which path you take.

Q. You told me earlier and you told Mr. Trischler that there's room within this model for the necessary component for individual physician decisionmaking. I'm still a little confused by that, so let me zero in on that a little bit. It seems to me to apply your model, you need to know what tests are going to be administered to the members of the

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patient population. Is that fair?

A. Not exactly. You need to know what tests are certified as part of the monitoring program and how frequently they are to be administered and what the size of the certified class ends up being.

Q. Okay.

THE VIDEOGRAPHER: The time is 5:57. We're going off the record.

(Whereupon, a brief recess was taken off the record.)

THE VIDEOGRAPHER: The time is 5:59. We're back on the record.

BY MR. OSTFELD:

Q. So Dr. Song, I believe what you just told me is that what your model needs is the procedures to be performed, the frequency with which they're going to be performed, and the quantity based on the number of members in the class. Am I remembering your testimony correctly?

A. Those are aspects of quantities that you would then pair with prices to estimate spending.

Q. So I guess my question is this: With

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respect to frequency, is there a method that can be applied to estimate on a class-wide basis with what frequency individual doctors will make determinations as to which tests are appropriate for which members of the patient population?

MR. MIGLIACCIO: Objection. Assumes facts not in evidence. Incomplete hypothetical.

THE WITNESS: We have talked about this earlier today, and this is well outside the scope of what I'm opining on in this report, and I would refer you to the oncologist expert for that question.

BY MR. OSTFELD:

Q. Okay, so we should ask the oncologist what percentage of time a given test is appropriate for a given patient for a given cancer?

MR. MIGLIACCIO: Same objection. You can answer.

THE WITNESS: I think that's well within the confines with our earlier discussion and with your colleague where we talked about the elements of the quantities in the medical monitoring program being defined by others in this case outside of what I'm doing on the pricing of medical services.

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BY MR. OSTFELD:

Q. You would agree to accurately estimate the pricing of medical services, you need to know the rate or frequency with which each test will be administered within the patient population?

A. No, I do not agree with that, sir.

Q. You need the quantity of total tests?

A. I think you might be switching the phrases "prices" with "spending." Certainly if you want to determine spending, you need both prices and quantity, but your question used prices. To accurately estimate prices, you do not necessarily need to have a predetermined quantity. In fact, my report is a demonstration of that. I'm focusing on prices in my report with still outstanding the components of a quantity that have yet to be certified.

Q. All right. That's a very fair point. To determine spending for the class, you need to know the frequency with which each screening procedure within the medical monitoring program -- strike that.

To estimate total spending --

A. I'm sorry, my child is charging up the stairs. I'm going to mute myself for a minute.

THE VIDEOGRAPHER: Time is 6:02. We're

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going off the record.

(Whereupon, a brief recess was taken off the record.)

THE VIDEOGRAPHER: The time is 6:03. We're back on the record.

BY MR. OSTFELD:

Q. So Dr. Song, to estimate total spending, you need to know the total quantity of each test that is going to be performed within the patient population. Is that fair?

A. As a fair summary of the common methodology to estimate the spending, one needs quantity and one needs prices, and as a general matter, if you give me the quantities or one provides me the certified monitoring program with the quantity of services, I could apply the best estimate with the available data of the prices of those services to those quantities to generate spending.

MR. OSTFELD: I have no further questions. I will pass the witness.

THE WITNESS: Thank you, sir.

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CROSS-EXAMINATION

BY MS. LOTMAN:

Q. Good evening, Dr. Song. My name is Alyson Lotman. I'm an attorney with Duane Morris in Philadelphia. I have a few questions for you and I will try to get through them as quickly as possible here.

So, Doctor, would a commercial insurance company cover a non-FDA approved test?

A. I'm sorry, would you mind repeating that question, please?

Q. Would a commercial insurance company cover a non-FDA approved test?

MR. MIGLIACCIO: Objection to the hypothetical. Incomplete.

THE WITNESS: I was not asked to opine on or think through FDA decisions as it pertains to this case. To the extent that by FDA decisions, you are inquiring about pharmaceuticals. My understanding is that there is another expert who is an expert with regard to pharmaceuticals in the case for the plaintiffs, so I would defer to the other expert on anything related to pharmaceuticals. If you're asking about FDA approval of tests, I'm -- off the top of my head, not able to characterize for you

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the pattern or frequency or rate of approvals of FDA approved tests among private insurers. I would at the very least ask that you provide some specifics about what private insurers and what test and when it was approved, and I could use my clinical knowledge to see if I have anything that might be helpful for you.

BY MS. LOTMAN:

Q. Your illustrative screening procedures, where did you get those? What was your source for those six screening procedures?

THE VIDEOGRAPHER: Time is 6:06. We're going off the record.

(Whereupon, a brief recess was taken.)

THE VIDEOGRAPHER: The time is 6:07. We're back on the record.

THE WITNESS: Thank you for repeating the question. They were provided to me by counsel.

BY MS. LOTMAN:

Q. Doctor, did you read Dr. Kaplan's report in this case?

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A. I have not had a chance to read his report yet because, to my understanding, we submitted the reports at roughly the same time.

Q. Did you review his transcript in this case, the deposition transcript?

A. Yes, I did review his deposition transcript or at least a section of it or it may have been the whole report that was provided to me by counsel.

Q. You read the transcript?

A. I'm sorry, transcript, not report.

Q. I just want to make sure we're both on the same page. Are you aware that he recommends a different test along with some of the ones you've outlined here that's called the gallery test?

A. I do recall reading that in his report.

Q. Are you aware that that test is not FDA approved yet?

A. I have not had a chance to deeply investigate that test. So, no, that fact I have not looked into yet. My knowledge of that test is confined to my recollection of what I read in his transcript.

Q. Understood. Doctor, is your methodology able to determine the costs and allow for the costs

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of non-FDA approved testing?
A. Again, my methodology is agnostic to many factors that I've been asked about today, including FDA approval. It applies to any services that are in the end part of a potential medical monitoring program.
Q. Doctor, I think it's my last question for you. It goes back to things that people asked you today, and you talked a lot about patients and their individual doctors and if they made a decision to not, say, have a colonoscopy. Are you saying that your methodology allows for that, because you would just, in the example of the colonoscopy, you would deduct the individual plaintiffs' colonoscopies from the number of procedures that you are putting into your equation?
A. Can you maybe rephrase your question? Are you asking me to do a mathematical exercise?
Q. No, I'm trying to clarify too for my sake too, Doctor. Are you saying that if we're talking about a patient and their individual doctor making a decision, and for this hypothetical, we'll use an example of colonoscopy, and patient A decides to their doctor I'm part of this class that I'm not getting colonoscopies for whatever reason him and the

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doctor decided on, are you saying that your methodology allows for that because your number is based upon the number of services actually provided so you wouldn't be including those patient A's potential colonoscopies in the number for the class?
A. Okay, let me provide you two parts to an answer. The first is that in a retrospective fashion, you can certainly do exactly what you just described. Once you know what services were delivered to whom, you're able to simply count or sum up the quantities of services delivered. In a prospective fashion, you may need to estimate that share, and I would also defer to my more expert oncologist subspecialties to comment on what proportion of total portions of services they recommended ought to go into a medical monitoring program consistent with all other aspects of quantity, which I have not been asked to opine on.
The other aspect of my answer is, to my knowledge, and this is off the top of my head, if you consider other medical monitoring programs that may have been created through litigation or other similar processes or cases, my educated guess, my hypothesis would be that in those cases, those monitoring programs likely also left some room or discretion for

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patient and physician or clinician preferences and joint decisionmaking. This would not be unique in this regard.
Q. And Doctor, do you have any information about any other medical monitoring classes that support your last statement there?
A. Off the top of my head, no details that I can recall at the moment.
MS. LOTMAN: Doctor, those are all of my questions for you this evening. We'll go off the video at this point.
THE VIDEOGRAPHER: The time is 6:13. We're going off the record.

(Whereupon, the deposition was concluded at 6:13 p.m.)

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CERTIFICATE

I, JOMANNA DEROSA, a Certified Court Reporter and Notary Public of the State of New Jersey, do hereby certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically and digitally at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

JOMANNA DEROSA, C.C.R.
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State of New Jersey

ERRATA SHEET

VERITEXT/NEW YORK REPORTING, LLC

CASE NAME: In Re: Valsartan, Losartan, Et Al

DATE OF DEPOSITION: February 8, 2022

WITNESS' NAME: Zirui Song, MD, Ph.D.

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ZIRUI SONG, MD, Ph.D.

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Before Me This______Day

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Notary Public

My Commission Expires__________________